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**FEDERAL INSECTICIDE, FUNGICIDE,
AND RODENTICIDE ACT**

ORIGINAL
COMPLETED

HEARING
BEFORE THE
**SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE**
OF THE
COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES
NINETY-SEVENTH CONGRESS

SECOND SESSION

ON

H.R. 5203

FEBRUARY 4, 1982

Serial No. 97-R

PART 3



Printed for the use of the Committee on Agriculture

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WASHINGTON : 1982

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FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

THURSDAY, FEBRUARY 4, 1982

HOUSE OF REPRESENTATIVES, SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH, AND FOREIGN AGRICULTURE OF THE COMMITTEE ON AGRICULTURE,

Washington, D.C.

The subcommittee met pursuant to notice, at 9:45 a.m., in room 1301, Longworth House Office Building, Hon. George E. Brown, Jr. (chairman of the subcommittee) presiding.

Present: Representatives Fithian, Panetta, Wampler, Roberts of Kansas, and Emerson.

Also present: Representative de la Garza, chairman of the full committee.

Staff present: Robert M. Bor, chief counsel; John E. Hogan, minority counsel; Peggy L. Pecore, clerk; Thomas E. Adams, Jr. Nick Ashmore, Charles Benbrook, Bernard Brenner, and Gerald R. Jorgensen.

OPENING REMARKS OF HON. GEORGE E. BROWN, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. BROWN. The subcommittee will come to order.

It's a great pleasure to see all the warm, friendly faces in the audience. I'm real attached to some of you as a result of our extensive involvement with this legislation. I have a brief opening statement which if you will bear with me, I will read it to you.

Nearly 1 year ago this subcommittee began a review of the Federal Insecticide, Fungicide, and Rodenticide Act. We conducted 5 days of oversight hearings last summer and fall, including a field hearing in Sacramento on September 4 on the State's rights issue. Based on the subcommittee's examination of the views of all interested parties on a range of administrative, legal, and policy issues, we produced a draft committee print containing a number of amendments to FIFRA. The committee print was the subject of three subcommittee business meetings last November and December. After making a number of substantive changes in the committee print in response to further meetings with interested parties, Mr. Wampler and I formally introduced H.R. 5203, on December 14, 1981.

We decided to introduce H.R. 5203 at the conclusion of the first session last December in order to have available for wide circulation and review a bill representing the culmination of long and complex negotiations on a number of contentious features of the

committee print. I hope that the interested parties have now had sufficient opportunity to review H.R. 5203, and will share with the subcommittee their views on the substance of the bill.

Following today's hearing, I will discuss the scope and timing of further action on H.R. 5203 with Mr. Wampler and other members of the subcommittee as well as the chairman of the full committee. Many people have worked diligently and in good faith to improve this act. I and the other members of the subcommittee want to fully capture the progress that has been made to date.

After providing other members a chance to make an opening statement, let us begin with our first witness. Mr. Wampler.

Mr. WAMPLER. I have no statement at this time.

Mr. BROWN. Mr. Fithian.

OPENING REMARKS OF HON. FLOYD J. FITHIAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA

Mr. FITHIAN. I have one comment. I do not mean to be rude, but I think we have heard all the witnesses previously on many occasions. I would hope that we could either mark up the bill shortly or quit the business all together.

I am willing to, of course, hear them one more time, but it seems to me that ultimately our job as legislators is to render a decision after we have heard all the parties. There may be parties here speaking today that I have not heard previously, but if so it escapes me as to whom they are.

So, I would hope that we can whip through this testimony. I think we have drafted the bill now and all we really need to know is a tabulation of who is for what and who is against what. Once having done that, I think the subcommittee has to wrestle to ground the decision to move the bill forward.

So, I would hope this would be the last day of hearings for FIFRA and that we would then move on to the legislative side of it.

I thank the Chairman.

Mr. BROWN. Thank you, Mr. Fithian. I think what you have said probably expresses the views of a number of other members of the subcommittee. However, I did not want to be quite that blunt myself. [Laughter.]

Mr. FITHIAN. Mr. Chairman, I am known for my candor. [Laughter.]

Mr. BROWN. I read this morning in the local newspaper a rather interesting article by Donald Kennedy, the president of Stanford University, and by virtue of that fact he is an outstanding leader of their community. It has a title, "Science in the Dock," and it makes a number of points which have come up occasionally in connection with these hearings about some of the problems that confront us in making legislative policy in an area replete with scientific questions.

For that reason, if there is no objection I would like to include that short article by Dr. Kennedy in the hearing record.

[The article follows:]

(Washington Post, Thursday, February 4, 1982)

Donald Kennedy

Science in the Dock

Fraud, experimentation on cancer patients, abuse of animals—a prominent scientist addresses the recent spate of charges against his profession.

Those who care for the health of scientific research in this country have watched with growing alarm as more and more news stories report incidences of fraud, mistreatment of patients during clinical research and abuse of animals in laboratory experiments. The stories, as far as can be told, are legitimate. The strength of the reaction to them suggests that some important nerves are being touched.

Some of the responses from the scientific community have been overly defensive. Fraud, we are told, is an aberration so infrequent as to be unworthy of serious attention; ethical objections to experiments involving human or animal subjects are answered by describing the benefits of the research, which amounts to changing the subject. Science is not now a sacred cow, if it ever was one; and scientists ought to stop behaving as though it were. The existence of abuses, however, does not reveal a fundamental, structural flaw in the conduct of science, as some have suggested. The real question is how to establish ethical standards and make choices about how much violation of the standards we can accept. This challenges us to decide how much freedom from abuse we wish to purchase, and at what cost to the scientific enterprise and to society itself.

Let me begin with fraud. Scientists are rewarded for their work not, in general, by large salaries or royalties, but by a measure of personal security and, more important, by such things as the joy of discovery and the regard of their peers. Scientists care a great deal about such things, and anything that many will work hard for, a few will cheat for.

There has always been some fraud around, and it has, for better or worse, been the academic tradition to handle it quietly. The literary plagiarist or the biochemist who cooks his data are permitted to pass quietly out of the system (or, more unfortunately, to continue to work about its edges). With the heavier involvement of public dollars and the greater insistence on accountability for them, more cases are being exposed. Has the actual incidence of fraud, as a fraction of the total work, increased? No one knows, and furthermore there are no data upon which to risk even an educated guess.

[REDACTED]

...of the future. That is not a test of

fraud—one can reach a wrong result by innocent error, or a correct one by dishonesty—but it is an effective way to uncover and discard the incorrect. [REDACTED]

Given that an effective system of error detection exists, should we invest heavily in a system of fraud detection? I do not believe that would be practical. To detect a small number of events we would have to audit a large amount of work. The expense, in manpower and in chilling effect upon the research enterprise, would be extraordinary, and the social gain would be limited.

The critical problem in the use of human subjects in biomedical research is quite different. The rules to be followed under the current system of protection are clear, and there is widespread sympathy for them in the scientific community. Institutional review boards, which must approve the plans for all experiments involving human subjects, operate, over nearly

their entire range of responsibility, in an atmosphere of approval and cooperation.

The Washington Post's series of articles on cancer research by Ted Gup and Jonathan Neumann ["The War on Cancer," Oct. 18-21] illustrates what happens in those rare instances when there is a special class of subjects who stand in a unique position with respect to the costs and benefits of treatment. Advanced cancer patients have the same rights as other subjects. But the prospective benefits of relief from a debilitating, life-threatening disease justify additional risks; the only argument is how much additional risk. The Post's series was for the most part anecdotal; but where it did attempt a more global analysis, it relied heavily on views from inside the Food and Drug Administration about the National Cancer Institute program.

It would have been fairer had the authors researched and reported the long and often highly personal history of that disagreement. At the time I served as FDA commissioner, some of the same FDA officials quoted in The Post's series were claiming that the NCI program had been placed "off bounds" to them, or that it received favorable treatment. I could find no basis for such claims then, and I doubt there is any now.

Had The Post's series attempted to grapple effectively with the risk/benefit question, it could have performed a valuable service. Instead, that function was left to a later editorial which, despite a certain obscurity of intent, at least recognized that "an experimental drug's chance of success and high risk of causing side effects must be balanced against the patient's high risk of death." Just so; that is the essence of the problem with trials of cancer drugs. It is a poignant one indeed, but it does not suggest a global failure of our system of protection for the human subjects of biomedical research.

No equivalent system exists for the protection of animal subjects. There are strong principles, but their enforcement rests mainly within the profession. Scholarly journals refuse papers whose authors fail to provide evidence of proper treatment of animals. This is supplemented by a system of government inspections.

But these apply to conditions under which animals are kept and not to the experimental protocols in which they eventually participate.

Our discomfort about animal experimentation is based upon a complex array of feelings. Taxonomic distance surely has a lot to do with it: in the United Kingdom, antivivisection laws apply stringently to warm-blooded vertebrates, but not at all to cold-blooded ones. In this country the Animal Welfare Act exempts rats and mice, suggesting perhaps that suitability as a pet may be involved in the degree of protection we accord a species here. These features do not add up to a very clear and consistent ethical position.

Nevertheless, there is solid agreement among scientists and advocates of animal rights that animals of whatever sort should be well cared for and subjected to minimum pain in the course of an experiment. Where real differences arise is over assessments of the need for animal experimentation. It is important that such judgments rest on a realistic understanding of what animal experimentation means to biomedical research; and unfortunately, the air is full of nonsense.

The only sure method we have for assessing the health risk of chemicals is to expose laboratory mammals at relatively high doses, and to estimate by extrapolation the risks of lower doses. No other method now available has the sensitivity or reliability to displace such tests.

It is silly to argue that if we merely throw money in the direction of developing alternatives to animal testing these alternatives will magically appear. Most animal experiments take advantage of basic physiological or biochemical similarities between the animals and people. They thus employ highly complex, delicate living systems, most of which cannot be modeled by *in vitro* systems, nor, as is sometimes suggested, by computer models.

The idea that one could usefully spend 30 percent of the NIH budget, or anything like that amount, on the development of alternatives to animal experimentation strikes most biologists as ludicrous. If we believe that we should no longer purchase improvements to human health through the experimental use of nonhuman vertebrates, we should make that decision in the clear knowledge that we are trading something away. In this area as in others, there is no free lunch.

Science is not magic, and it is not a human activity. It is an enterprise we pursue for social gain, and it has been, by and large, an effective one. If we don't like the present arrangements for its conduct, we can change them: we could probably reduce the incidence of fraud a little, reduce the risks to human subjects somewhat and reduce or even eliminate the use of animals. But we cannot do any one of these things without effects—profound ones, in my judgment—on the productivity and vigor of the research enterprise and on its capacity to improve the human condition. We can have what we want, in short, but we shouldn't kid ourselves about the price.

The writer, a biologist, is president of Stanford University and former commissioner of the Food and Drug Administration.

Mr. BROWN. Without objection, it will be made part of the record. Our first witness this morning is Mr. J. B. Grant, executive secretary of the National Association of State Departments of Agriculture. He is accompanied by Mr. J. Ronald Conley, director, pesticide division, Georgia Department of Agriculture.

We welcome you, gentlemen.

May I indicate without any desire to be overly restrictive that with the number of witnesses we have we will have about 15 minutes for each person testifying. We would like to have a few minutes of that time for questioning, so if you could accommodate yourselves to that schedule we would appreciate it.

STATEMENT OF JAMES B. GRANT, EXECUTIVE SECRETARY, NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE, ACCOMPANIED BY J. RONALD CONLEY, DIRECTOR, PESTICIDE DIVISION, GEORGIA DEPARTMENT OF AGRICULTURE

Mr. GRANT. Thank you, Mr. Chairman. I'm J. B. Grant, executive secretary of the National Association of State Departments of Agriculture and I am pleased to have with me one Mr. J. Ronald Conley, director, pesticide division, Georgia Department of Agriculture. He is also a member of the Association of Pesticide Control Officials.

I want to thank you, Mr. Chairman, and Mr. Wampler and other members of the subcommittee for another opportunity to testify on H.R. 5203 on behalf of the National Association of State Departments of Agriculture.

I will limit my remarks to section 11 of the bill, which concerns authority of the States to regulate the sale or use of federally registered pesticides.

Almost 8 months have elapsed since this subcommittee initiated the FIFRA reauthorization process, and during these past months you have given our association frequent opportunities to comment on each new proposal. At the hearings last June, and on many occasions since then, the association has been clear and consistent in its opposition to any amendments aimed at limiting the authority of States under FIFRA Section 24(a). Our position has not changed.

H.R. 5203 contains language in bill section 11 that would have the effect of undermining the integrity of State pesticide registration programs. Consequently, the association respectfully asks your help in deleting the section 11 language in its entirety.

The association fully recognizes the potential burden on the pesticide industry if States began to issue excessive and unnecessary data requests. In our policy position No. PI-17 adopted last September at our annual meeting NASDA recognized that the Environmental Protection Agency has set minimum standards for the regulation of pesticides and that such minimum standards meet the specific needs and expectations of each and every State. We further pledged in PI-17 to work with all affected parties in resolving the current problem relating to requests for data by States on federally registered pesticides.

We do not believe that the current problem in one State should be solved by legislation that disrupts registration programs in the 49 other States.

Proposed changes to section 24(a) would give the Administrator of EPA veto powers over certain State decisions regarding State registration. Section 24(a) as it is now written provides the States with the authority to regulate the sale or use of any federally registered pesticide within the State. It gives States the flexibility they need. The provision has been in effect since 1972 and has worked smoothly and has not been controversial until just recently. The proposed changes to section 24(a) would greatly undermine States authority, allowing the Administrator of EPA veto powers over decisions at the State level regarding pesticide registration. We do not believe this preemptive authority would be necessary or desirable.

Bill section 11 involves new legal pitfalls with the potential of greatly increasing the incidence of costly and lengthy litigation, and it also would require 50 States, as well as EPA, to draft new regulations and establish an entirely new regulatory procedure for State registrations. The costs of this new layer of bureaucracy would then ultimately be passed back to farmers and other pesticide users.

It has been well documented over the past 8 months that the proposed changes to section 24(a) would be costly, time consuming, involve a Federal veto, increase litigation, and generally undermine the ability of the States to administer our own programs.

We are not alone in our opposition to section 24(a). A number of national organizations have endorsed the NASDA position which was adopted unanimously by all the States in attendance at our annual meeting last September. I am sure that each member of this subcommittee has also heard from the individual States regarding our position.

Mr. Chairman, we are grateful to you, Mr. Wampler, and the other subcommittee members for the openness and diligence of these hearings and the many courtesies you have shown us during the long and difficult reauthorization process. We respectfully urge the subcommittee to support our position and delete Section 11 of H.R. 5203 and allow Section 24(a) to stand unamended.

Mr. BROWN. Thank you very much, Mr. Grant. Mr. Wampler.

Mr. WAMPLER. Mr. Grant, I want to welcome you and also Mr. Conley here. It's good to see Mr. Conley again. I know of his long years of experience at the State level and the total realm of the regulation of pesticides.

Mr. Grant, on the second page of your prepared statement you said, "we further pledge in PI-17 to work with all affected parties in resolving the current problem relating to requests for data by States on federally registered pesticides." Have you been able to make much success in those deliberations or could you give us a brief account of what success you've had since your meeting I believe in Boston last fall.

Mr. GRANT. Mr. Wampler, I think there has been a great deal of progress made. I cannot preempt the State of California's testimony you are going to hear this afternoon. I did talk to Director Rich Rominger last night and I understand from Mr. Rominger that a good deal of progress has been made on some of the complaints that industry has made regarding the registration of pesticides in California.

My personal feeling at this point after that conversation is that there has been a great deal of progress made.

Mr. WAMPLER. As you know, I think every member of this committee holds you and NASDA in very high esteem. We want to encourage you to continue to work and to try and cooperate in resolving these problems regardless of what we do in this bill because I think it is terribly important that we have our affected State agencies working as closely as possible together with EPA and other interested parties to resolve these differences.

I do not know what the ultimate disposition of section 24(a) is going to be by this committee or by the Congress but I want to commend you for a position that NASDA took in this matter and encourage you to continue to work and try to resolve those problems.

Thank you very much. Thank you, Mr. Chairman.

Mr. BROWN. Thank you, Mr. Fithian.

Mr. FITHIAN. I have no questions at this time, Mr. Chairman.

Mr. BROWN. Mr. Grant, I would like to follow up momentarily with Mr. Wampler's line of thinking. I think you are well aware of the fears and concerns expressed in some quarters with regard to excesses of zeal by the States on the matter of requesting data or issuing regulations.

This was to some degree triggered by California and to some degree triggered by anticipation that other States might follow this lead and produce a situation that really would be a burden on commerce. This is a legitimate fear. I'm sure you are aware of that.

You make the statement that your association fully recognizes the potential burden on the pesticide industry if States began to issue excessive and unnecessary data requests.

Are you in a position to comment with regard to what the States are likely to do, and we'll skip the terms "excessive and unnecessary"? I know if any State issues a request for data they will not do it excessively unnecessarily but is there a move or an indication that the States might begin a process of major activity in this area?

Mr. GRANT. Mr. Chairman, insofar as we can determine the problem only exists at this time in the State of California. We're all aware of that.

We have made a very extensive inquiry of the States since we became involved in the reauthorization process last summer. This was to determine if there was such a move on the part of these States.

We have been unable to determine that there is.

I know that there have been indications that some States are leaning that way, but insofar as we have been able to determine among the principals there is no sort of movement underway and very frankly I doubt that there are many States that are geared up to have the technical setup within their organization to get into that in-depth type of program, except California.

I personally do not feel that there is any kind of a movement under way. Certainly the 50 State departments of agriculture are not interested in creating 50 little EPA's out there, as has been said. I just do not see that. We have not been able to make a positive determination that there is any type of movement under way.

Mr. BROWN. Mr. Conley, could you comment on that question with regard to your experience.

Mr. CONLEY. Based on my experience, Mr. Chairman, most of the States do not have the mechanisms by which they could handle extensive data for review. We are certainly not equal to EPA in our manpower resources.

To my knowledge—and I think I can speak a little more clearly for those States in my region of the country than I can for some of the Western States with whose program I am not totally familiar—but I have talked to no one among my counterparts who has indicated that they have any intention of expanding their authority or expanding their practice of requiring data beyond that that they are presently requesting.

I have found that in recent years my need for additional data has diminished. In those cases where I have needed data I have asked the companies for it and there has not been a single case where I was not able to get what additional data I needed.

Mr. BROWN. I have no further questions at this time. Gentlemen, we appreciate very much your contribution and we thank you for being here this morning.

Our next witness this morning is Ms. Stephanie Bower, Washington representative, United Farm Workers.

STATEMENT OF STEPHANIE BOWER, LEGISLATIVE REPRESENTATIVE, UNITED FARMWORKERS OF AMERICA, AFL-CIO

Ms. BOWER. Mr. Chairman, I am pleased to speak to you today to address the issue of the proposed amendments to the Federal Insecticide, Fungicide, and Rodenticide Act and to bring you greetings from our president, Caesar Chavez, and vice president, Vars Verto.

We appreciate the efforts of the chairman and this subcommittee to work out a compromise on sections 10 and 24 and other provisions of FIFRA.

However, we must say that the present bill, H.R. 5203, presents serious problems for the United Farmworkers of America, AFL-CIO. Until and unless these problems are resolved we regretfully must oppose H.R. 5203.

We do so reluctantly because UFW regards you as our friend and you have made more than a good faith effort to get industry, labor and environmentalists to compromise on an acceptable bill.

We must oppose H.R. 5203 because it places the burden on the worker, consumer, and the public when it should be placed on those who produce the chemicals.

We are concerned that pesticide enforcement be transferred from EPA to OSHA. As Dr. Ephraim Kahn, consultant to the California Department of Health Services, told this subcommittee in Sacramento at your September 4 hearing, the EPA has been weak in evaluating and controlling health hazards. It is totally lacking in orientation toward this issue and lacks staff acquainted with industrial hygiene and occupational medicine:

As a result, several hundred thousand agricultural workers * * * have been placed in second class status. They are exposed to highly toxic materials but are denied the safety protection accorded other workers under the Occupational Safety and Health Act.

H.R. 5203 mandates a private right to sue which we strongly support. In routine pesticide poisoning cases involving our workers, we will not be able to get EPA nor the State agricultural departments to effectively enforce the existing pesticide misuse laws. In routine pesticide misuse violations we have more faith in OSHA enforcement than we do in enforcement by State agricultural departments.

The UFW has a strong interest in reasonable access to information about pesticides for our farmworker members such as cancer incidence studies, genetic defect data, and exposure incidence data.

At present, this material is available to us by means of a simple request to EPA under FIFRA. The proposed amendments to section 10 of FIFRA would cause us unnecessary and unreasonable difficulty in getting this information.

If we are denied access to the reading room, we have no right under H.R. 5203 to know why our request was denied. The decision of the administrator is final and not subject to judicial review. Such a one-sided procedure, denying labor a fundamental due process right, is unacceptable to us.

The amendments would also deny us the right to photocopy significant portions of the health and safety data. This restriction places a tremendous time burden upon organizations such as ours with limited staff.

Our members are exposed to many pesticides in the course of the year. For example, tomatoes in California are treated with more than 60 different chemicals. A farmworker may work in three or four other crops during the year, and he is exposed to many additional chemicals in each different crop. We do not have the staff nor the time to make handwritten notes from so many different sets of data. Photocopying is the only simple, fast, inexpensive way to obtain the broad range of data we might legitimately seek on behalf of our members. We want to keep that right.

Our members suffer frequent acute short-term illness from exposure to pesticides in their daily work. They touch residues on plants, soil, irrigation pipes, and equipment. They often breathe in pesticides while working. They may be incurring long-term chronic damage from their constant exposures, leading to early disability, ill health, shorter life span. They are suffering damage to their unborn children. We oppose the proposed amendments to section 10 because they are unnecessary, expensive, and infringe upon our crucial right to know what hazardous substances we are exposed to in our work place.

Although we have problems in California with State Department of Food and Agriculture's enforcement of pesticide misuse laws, we recognize that CDFA has been more stringent than EPA in requiring pesticide producers to furnish health and safety data concerning the hazardous effects of pesticides on human beings and the environment. However, recently a moratorium has been placed on pesticide hearings in the California House of Representatives.

We reject H.R. 5203 amendments to section 24 which limits States' rights to set a higher ceiling than the Federal Government concerning the registration, sale and use of pesticides. Many of our farmworker children across the country die from accidental pesticide exposure. Some of these pesticides are for house and garden

use. Under H.R. 5203 amendments, EPA can deny a State request for additional safety and health data if EPA finds this request is arbitrary or capricious or if comparable data is available elsewhere. To force States to seek EPA approval before they can seek such data does not make sense. California in the past restricted or banned pesticides after farmworkers died. Now California is routinely demanding more health and data than EPA requires in attempting to prevent harm before these deaths occur. We applaud this effort and therefore must reject the H.R. 5203 proposed amendments to section 24.

Thank you very much for this opportunity to speak to you. I would be glad to try to answer your questions.

Mr. BROWN. Thank you very much, Ms. Bower. Mr. Fithian.

Mr. FITHIAN. Thank you, Mr. Chairman.

Ms. Bower, your major objection seems to be section 10 in the bill, the proposed new section 10. Would your organization be in support of the bill if that section were not in this bill?

Ms. BOWER. It would, but we also have a concern for section 24. But we would be in favor of not amending the bill to that extent.

Mr. FITHIAN. Maybe I didn't ask my question correctly.

If an amendment were to prevail and either the subcommittee or full committee striking the changes to section 10 that are now proposed concerning the reading room and so on, would that then tip your organization to favor the bill as it is drafted, or would you still oppose the bill?

Ms. BOWER. We would still probably oppose the changes to section 24.

Mr. FITHIAN. I see. Thank you. Thank you, Mr. Chairman.

Mr. BROWN. Ms. Bower, do you have any specific experience with obtaining pesticide studies from EPA through the existing Freedom of Information Act procedures?

Ms. BOWER. No, I do not. I would have to check with those people who are directly working in the field.

Mr. BROWN. I see.

Ms. BOWER. In my current capacity I have only been here since this whole business came up.

Mr. BROWN. We are not trying to elicit more information than you may have so do not worry about that.

We are still honestly trying to evaluate the processes existing and proposed to determine the reality of their effects rather than perhaps having misconceptions.

Unfortunately, there are still situations in which there have been created some fears which we are not sure are well grounded. We are trying, of course, to ascertain whether or not they have.

Ms. BOWER. I do know that. We are very short staffed. These proposed changes really would be a problem insofar as our being able to get the data the way it is set down in the draft.

Mr. BROWN. The requirements prohibiting the copying of certain data?

Ms. BOWER. Yes.

Mr. BROWN. Do you feel that you have a strong basis for your statement that you might be denied access to the reading room or to essential data contained in the reading room?

Ms. BOWER. I feel that that is a real possibility, yes.

Mr. BROWN. I have no further questions, and if there are no further questions, we will thank you very much for your testimony.

Our next witness is Mr. Richard Lewis representing the International Chemical Workers Union of Akron, Ohio.

STATEMENT OF RICHARD LEWIS, OCCUPATIONAL AND ENVIRONMENTAL HEALTH SPECIALIST, INTERNATIONAL CHEMICAL WORKERS UNION

Mr. LEWIS. Mr. Chairman, I am an occupational and environmental health specialist on the staff of the International Chemical Workers Union (ICWU).

ICWU appreciates the opportunity to talk to you today about health and safety protection of workers and the public from hazardous exposure to pesticides.

ICWU experience in this area demonstrates fundamental shortcomings in the current approach to the control of pesticide related health hazards. Safe manufacture and use of pesticides will require a systematic approach by industry, labor, and Government which incorporates the practice of pretesting hazardous pesticides, responsible industrial medicine practices, and the practice of the free flow of health and safety information to workers and public health professionals. Without this three-pronged approach neither ICWU nor any other entity concerned with occupational health will be able to implement programs designed to prevent occupational disease rather than compensate workers after the damage is done.

Our experience indicates that the three above-named practices have not been widely instituted in the chemical industry. Pesticide products continue to threaten the well-being of workers by producing disabling burns and irritation to the skin and eyes and by producing long-term hazards such as cancer, reproductive disorders, and neurotoxic effects.

Data from the Bureau of Labor Statistics' "Occupational Illness and Injury in U.S. Industry" indicate a total of 6,920 occupational injury and illness cases in 1979 alone which resulted in 43,547 lost workdays in the agricultural chemicals industry (SIC Code 287). This was taken from "Occupational Injuries and Illnesses" in 1979: Summary, U.S. Department of Labor, Bureau of Labor Statistics, April 1981, page 10.

Although this data represents a serious public health problem and obviously a tremendous amount of pain and suffering for workers, ICWU in conjunction with other organizations involved in occupational health contend that a lack of recognition of the occupational etiology of disease by doctors, company personnel, and workers is a significant barrier to documenting the true magnitude of the health consequences of unsafe pesticide manufacture and use.

In section I of this testimony, ICWU demonstrates the nature of health problems our members experience resulting from pesticide exposures.

The second section of the testimony includes specific comments on section 10 of FIFRA and the amendments in section 5 of H.R. 5203.

The third and final section of the testimony discusses the trade secret issue in a context of access to health and safety information under FIFRA and other occupational health legislation.

I will now turn to the first section of the testimony, ICWU Experience with Pesticide Health Hazards.

First, pretesting hazardous pesticides. Thorough testing of pesticides and complete scientific review of health and safety data prior to manufacture and use are essential components of a preventive approach to controlling health hazards resulting from exposure to pesticides. The tragic story of birth defects among children of members of an ICWU local in New York State demonstrates this critical point.

Oryzalin, a liquid herbicide used to control weeds and brush in soybeans, cotton, fruit, nuts, and woody ornamental plants, was produced by ICWU Local 227 over an 18-month period from January 1975 to June 1976 at the GAF plant in Rensselaer, N.Y. During that 18-month period several cases of birth defects by the local union of 30 workers in the production area showed that no normal pregnancies occurred over the 18-month production period.

The following information has been reported to the International Health and Safety Department by the local and has been the subject of investigation by EPA, NIOSH, and OSHA: (1) In June 1975, a chemical operator's wife miscarried; (2) on June 24, 1975, an operator's wife bore a son with a heart defect (transposition of the great vessels); (3) on December 24, 1975, a son was born and died on February 26, 1976, of pneumonia; (4) on April 3, 1976, a son was born with a heart defect (transposition of the great vessels)—he died on October 14, 1977; (5) on June 19, 1976, a son was born and died shortly thereafter of a heart defect—hypoplastic left heart; and (6) only one child born during that time period is living today. That child is now 5 years old and has undergone extensive surgery and is still under treatment. I will summarize this information. There were five reported birth defects, three having to do with defects of the heart. Of the five children born during that period only one is alive today. That child has undergone \$300,000 worth of surgery and is still under treatment.

ICWU investigation into the pretesting—prior to production and marketing—of oryzalin and subsequent studies conducted by Government agencies and the registrant, Eli Lilly Co., is still ongoing. In the area of animal testing, ICWU is awaiting results of teratology—the scientific investigation of birth defects—studies recommended by the OSHA Directorate of Technical Support during their investigation. It is the understanding of ICWU that EPA has required the registrant to conduct these studies, but ICWU has been unable to determine the status of these studies or even if they have begun. The union health and safety department is particularly concerned about the studies in the Dutch-Belted rabbit and a third species of animals. Expert scientific opinion has indicated that evaluation of these studies is essential in assessing the teratogenicity of oryzalin.

A preventive approach to health problems associated with pesticides requires thorough testing and open scientific review of health and safety data before production begins. In the case of oryzalin, ICWU is still today, some 5 years after the tragedy, in the process

of filing detailed freedom of information requests with the EPA in an attempt to ferret out all the known health hazard information on oryzalin.

Second, industrial medicine practice. Treatment of illness resulting from pesticide exposure including both first aid preparedness and medical monitoring are critical components of a sound industrial medicine program for a pesticide manufacturing operation. The following practice involving du Pont's treatment of ICWU Local No. 900 workers exposed to carbamate pesticides from 1979 to 1981 demonstrates that medical treatment if misused can become a contributing factor to serious occupational illness.

The company produced a carbamate pesticide called methomyl which is associated with neurotoxicity. Methomyl acts as a nerve poison, blocking the action of the enzyme called cholinesterase, and hence, is known as a "cholinesterase inhibitor." Cholinesterase stops the transmission of a nerve impulse by breaking down a nerve "transmitter substance" known as acetylcholine. Without cholinesterase, as is the case when methomyl is active, the nerve impulses continue to be transmitted, resulting in the continual stimulation of some of the nerves of the body.

Continual stimulation of the nerves as a result of cholinesterase inhibition through exposure to methomyl, can produce a variety of symptoms such as headaches, dizziness, weakness, twitching, excessive salivation and sweating and vomiting. The company's approach to treating workers suffering from these symptoms was to administer a prescription drug called atropine sulfate. Atropine is an antidote for carbamate poisoning which is used to reverse the symptoms of acute poisoning. Atropine blocks the action of acetylcholine, which is responsible for the continual stimulation of the nerve cells and allows the transmission of nerve impulses to return to normal, thus alleviating the acute symptoms. However, the antidote may not affect the possibility of developing chronic symptoms later on. Once the atropine had been administered to workers, they were permitted to rest for a short time, and they were put back to work. Atropine was being used in this way to mask temporarily early symptoms of poisoning. This practice is detrimental if the worker is sent back to the job and exposure is continued. This practice could result in serious impairment of worker health.

The medical literature clearly indicates that atropine should be prescribed only for the purpose of first aid. I would like to include in the record information on antidotes taken from the "Pesticide Information and Safety Manual."

[The material submitted is held in the subcommittee file.]

Mr. LEWIS. The company's practice in this case went beyond emergency first aid treatment and the dispensing of medication was actually used in an attempt to control a routine hazard. One worker told the health and safety department that "the tablets (atropine) were available as though it were chocolate candy." The local also reported that atropine which is a prescription drug was distributed at times by nonmedical company officials.

Responsible and informed medical treatment of pesticide workers, farmworkers, and the public is a necessary component in the control of hazardous pesticide exposures.

Third, worker access to health and safety information. ICWU believes that workers and the public have a right to know of the pesticide hazards they face on the job or in the community. This includes the right to know information on the chemical identity and health hazards of workplace chemicals along with the right to be informed of the results of medical tests given to monitor the effects of toxic exposures. All of this information is important to the health and safety training of workers and the workers' ability to provide a physician with information about occupational exposures needed to treat the worker. This type of information is not routinely communicated to workers as the experience of ICWU Local No. 61 indicates.

Local 61 members employed at Sterling Organics, Inc., in New York, manufactured an organophosphate pesticide called Phosmet in 1981. Organophosphates are associated with neurotoxicity similar to the earlier description of carbamate pesticides made at local No. 900.

Although the effects of overexposure to organophosphates are commonly known in the field of occupational health, the Phosmet warning label and attached information on recommendations and directions for use do not mention these effects or the symptoms to watch out for.

[The material submitted is held in the subcommittee file.]

Mr. LEWIS. Pesticide labels commonly are inadequate in the area of chronic health hazard notification such as neurotoxicity.

In the case of local No. 61, a blood testing program to monitor the effects of organophosphate exposure by measuring blood cholinesterase levels was instituted by the company. However, workers were not informed of the results of these tests. When the company nurse was questioned on this point, her response was, "If there is anything wrong, we will let you know." This is hardly reassuring since the monitoring schedule indicates that many workers did not receive a preexposure baseline test which is critical in the analysis of blood cholinesterase levels. Regardless of the test protocol shortcomings, ICWU local members were not informed of their own test scores. Only after the local union filed a complaint with the National Labor Relations Board did the company agree to provide medical test results.

The free and direct flow of health and safety information to workers is critical to the practice of occupational disease prevention. Workers exposed to pesticides do not routinely receive complete hazard information from labels or from their employers. Access to health and safety data maintained by EPA is an important component of a worker's ability to protect her or his health or the health of other members of the union.

I turn now to the protection of trade secrets and other information.

FIFRA is the central component of legislative authority under the various environmental health statutes which provide for adequate regulation of pesticides. Authority to make available to the public health and safety data under FIFRA section 10(d) is a critical link in the regulatory scheme of recognition, treatment, and prevention of occupational illness resulting from pesticide exposure.

It should be noted that there does not exist a generic pesticide standard under OSHA. I refer you to a 1975 decision, *Organized Migrants in Community Action, Inc. v. Brennan*, 520 F.2d 1161 (D.C. Cir. 1975), which precluded OSHA from regulating farmworker pesticide safety. The court ruled that section 4 of the OSHA precluded OSHA from acting in areas where a different Federal agency had statutory authority and was exercising that authority. Also workers have been unable to utilize their NLRA rights to fully protect their health and safety.

ICWU is committed to the concept and practice of full access and utilization of health and safety data by workers, their designated representatives, and occupational health professionals including physicians and scientific researchers.

H.R. 5203 proposes two severe barriers to this practice. The first is restrictions on access and utilization of health and safety data by the independent scientific community, and the second is restrictions on access and utilization of health and safety data by workers and their designated representatives.

First, I will talk about restrictions on the scientific community. Restrictions on free access by the independent scientific community and further restrictions on the use of data will have a drastic, chilling effect on the peer review process which is critical to producing credible scientific opinion in the highly controversial and rapidly developing field of pesticide toxicology.

The inhibition of the advancement of the state of knowledge fundamentally impedes the development of the earlier outlined three-pronged approach to controlling hazards. The approach included pretesting, responsible industrial medicine practices, and the free flow of health and safety information.

Second, I will discuss restrictions on the worker designated representative. H.R. 5203 proposes that worker designated representative's utilization of data, if consultation of a second party is involved, be restricted to the photocopying of charts and graphs and the taking of nonverbatim notes of an entire study. The designated representative is permitted to use this material for various purposes including medical treatment and the evaluation of potential health effects. Utilizing incomplete information for these purposes is irresponsible and dangerous.

Recent methodological and technological developments in toxicology research have enabled researchers to study the long-term health hazards (for example, cancer, reproductive disorders, and neurotoxicity) of many chemicals used in industry today. These studies are conducted in part or in whole to generate scientific data to be used to set safe levels of exposure for workers, yet the proposed amendments forbid the designated representative from consulting appropriate experts to allow for a full and open evaluation of the scientific data.

I turn now to the trade secret issue in context.

The trade secret protection issue has become central to several health and safety controversies today including the debate over H.R. 5203. ICWU has no problem whatsoever with pesticide producers' desire to protect legitimate trade secret information on manufacturing processes, production, distribution, and sale from their industrial competitors. However, worker access to health and safety

data is a separate issue, and the two should be kept separate. ICWU is concerned that members of the chemical industry are making unreasonable trade secret claims which restrict legitimate scientific investigation into the health hazards of final products and manufacturing processes.

ICWU has been actively involved with this issue for several years, first under the National Labor Relations Act bargaining rights and more recently under the OSHA's Access to Employee Exposure and Medical Records Standard.

First, the National Labor Relations Act.

The issue of a union's right to health and safety information—such as a list of chemicals used in the plant—for which the company claims confidentiality has been before the NLRB for more than 4 years. NLRA charges were filed against Borden Chemical, November 11, 1977, in a case involving this issue. The full Board has not yet handed down a decision on this case which has been consolidated with two others. (Minnesota Mining & Manufacturing Co. 18-CA-5710 and 18-CA-4711, Colgate Palmolive Co. 17-CA-8331, Borden Chemical, a division of Borden Inc. 32-CA-551.)

Second, the OSHA access to employee exposure and medical records standard.

ICWU has developed considerable experience under the OSHA's Access to Employee Exposure and Medical Records Standard. The standard includes the following language concerning trade secrets.

Trade Secrets. (1) Except as provided in paragraph (f)(2) of this section, nothing in this section precludes an employer from deleting from records requested by an employee or designated representative any trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in a mixture . . .

(2) Notwithstanding any trade secret claims, whenever access to records is requested, the employer shall provide access to chemical or physical agent identities including chemical names, levels of exposure, and employee health status data contained in requested records. (29 CFR 1910.20 (f))

ICWU is working toward a reasonable agreement on the trade secret issue in all cases where the employer has made access to information conditional on a trade secrets agreement. The union's legal department has drafted a model trade secret agreement which I would like to have inserted into the record.

Mr. BROWN. Without objection, we will insert the model agreement in the record at this point.

[The model trade secret agreement follows:]

TRADE SECRET AGREEMENT

Re: Information Requested Under the OSHA Access to Employee Exposure and Medical Records Standard.

WHEREAS the Company's manufacture and processing of materials involves confidential information or trade secrets; and

WHEREAS the ability to maintain a competitive advantage is in the interest of the Company and in the interest of the job security of the workers employed at this location; and

WHEREAS the workers at this facility have the right to know whether they are exposed to toxic chemicals or hazardous agents; and

WHEREAS the OSHA Access to Employee Exposure and Medical Records Standard provides for employee and designated representative access to employer - maintained exposure and medical records relevant to employees exposed to toxic substances and harmful physical agents.

THEREFORE, the Employer, _____
and the International Chemical Workers Union and its Local _____
hereby enter into the following agreement:

1. The Company shall provide the Union with the information requested in the attached letter marked "Attention: Plant Manager".
2. The Union agrees that confidential information provided by the Company shall be used only for the purpose of protecting the safety and health of bargaining unit employees. Any information designated "confidential" by the Company will be kept in locked files with access restricted to employees of the International Union, Local Union Executive Board and Safety Committee persons, except as provided below.
3. Under no circumstances will the disclosure of information to employees of the Company, or their families, constitute a violation of this agreement. The Union intends to cooperate with medical doctors and other experts in occupational safety and health and may provide them as well as government agencies engaged in health surveys, with materials and information supplied by the Company, subject to their willingness to be bound by an agreement similar to this one. If a governmental agency is utilized by the Union, it will not occur until the Company has been given 24 hour notice, and when it occurs the Union will notify the agency that the information is considered to be confidential.
4. Any information specifically designated as "confidential" by the parties shall be so stamped, dated and initialed by representatives of the parties. Such documents will be reviewed annually by the parties to determine if such classification should remain in force or be removed.

5. This agreement expires _____.

Date _____.

For the Company _____

For the Union _____

Mr. LEWIS. ICWU has developed internal procedures to safeguard the handling of trade secret information.

ICWU is unaware of any examples of union misuse of confidential health and safety information either under NLRA or OSHA.

Third, the Federal Insecticide, Fungicide, and Rodenticide Act.

H.R. 5203 proposed restrictions on worker access—section 10(g) of the present FIFRA statute also places unreasonably severe restrictions on access to health and safety data by employees of multinationals engaged in pesticide production—page 39, lines 23 to 25; page 40, lines 1 to 3; and page 40, lines 12 to 17. Proposed penalties are inappropriate and misdirected. The union has no interest in precipitating the financial ruin of the employers of its membership, but does have a strong interest in the health and safety of its members.

Present FIFRA law and H.R. 5203 contain language restricting the release of information concerning inert ingredients. An inert ingredient is defined in section 2(m) as one that is not active. Section 2(a) defines active in terms of effects on pests and plants.

The effect of the inert ingredients on people should also receive primary attention. 40 CFR 180.1001 includes a table of inert ingredients for which disclosure restrictions apply. This list contains a number of chemicals regulated by OSHA because of their harmful health effects in man. For example, methyl chloride and 1,1,1-trichloroethane appear on the 40 CFR 180.1001 inert list, yet both are associated with neurotoxicity in standard occupational medicine texts.

Methylchloride is a neurotoxin and causes convulsions. Human fatalities have occurred from a single severe exposure or from less severe prolonged exposure. Severe poisoning in man is characterized by a latent period of several hours, followed by dizziness, drowsiness, staggering gait, slurred speech, nausea, vomiting, diarrhea, double vision, weakness, paralysis, convulsions, cyanosis, and coma. Renal or hepatic damage and anemia also occur.

1,1,1-Trichloroethane causes central nervous system depression. A number of human fatalities related to industrial exposure in closed spaces have been reported, some of which may have been sudden deaths due to sensitization of the myocardium to epinephrine, "Chemical Hazard of the Workplace," N. H. Proctor and U. P. Hughes, Lippincott Co., Philadelphia, 1978, pages 336 and 488.

Based on our experience under the National Labor Relations Act and OSHA, ICWU encourages you to consider legislative language which clearly distinguishes the treatment of trade secret information from health and safety data.

This concludes the ICWU testimony. Thank you.

Mr. BROWN. Thank you very much. Mr. Panetta.

Mr. PANETTA. How do you presently get the information that you want from EPA?

Mr. LEWIS. Well, it's kind of a long story. We used the oryzalin story and we spent 4 months on the telephone with people from Eli Lilly and EPA and OSHA. We finally are just going to have to go ahead and file a freedom of information request. We have filed two other freedom of information requests with EPA in the last 3 weeks on pesticides, and it's too early to report on the experience.

Mr. PANETTA. So you have not gotten any information after all?

Mr. LEWIS. Not from the EPA.

Mr. PANETTA. Would you prefer to go through that process as opposed to any kind of orderly process established by the committee?

Mr. LEWIS. I will have to see what the experience is using the FOI route before I can answer that question. Maybe it will work for us.

Mr. PANETTA. It could take months.

Mr. LEWIS. Yes. I'm aware of that.

Mr. PANETTA. You prefer to take that gamble as opposed to working out any kind of approach in the legislation?

Mr. LEWIS. I personally prefer not to take any gamble. If somebody can work with a system that gives us full copies of health and safety studies that's all we're looking for.

Mr. PANETTA. Do you have suggestions as to a system?

Mr. LEWIS. I offered the trade secret protection language from the OSHA Access Standard. I think that's reasonable. I think it's working, and when OSHA was actively enforcing that standard it worked pretty quickly.

Mr. PANETTA. Thank you. Thank you, Mr. Chairman.

Mr. BROWN. Mr. Fithian?

Mr. FITHIAN. There is some feeling—and there may be some testimony later today—in favor of dropping section 10 and leaving the status quo. Would you favor that?

Mr. LEWIS. I think that the 1978 section 10 language is an improvement over H.R. 5203 definitely.

Mr. FITHIAN. Thank you.

Mr. BROWN. I have no further questions and so we thank you, Mr. Lewis for your testimony.

Our next witness is Mr. Ralph Engel, president, Chemical Specialties Manufacturers Association.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, ACCOMPANIED BY STEPHEN KELLNER, VICE PRESIDENT OF LEGAL AFFAIRS AND HARVEY GOLD, CHAIRMAN OF GOVERNMENT AFFAIRS ADVISORY COMMITTEE, PUBLIC AFFAIRS SECTION

Mr. ENGEL. Thank you, Mr. Chairman. I bid you all a good morning. As indicated, Mr. Chairman, I am Ralph Engel and I am president of the Chemical Specialties Manufacturers Association (CSMA), headquartered in Washington, D.C. I am accompanied today by Mr. Stephen Kellner, CSMA vice president of legal affairs, and Mr. Harvey Gold, chairman of our Government Affairs Advisory Committee, public affairs section.

CSMA has a membership of nearly 435 firms engaged in the manufacture, formulation, distribution and sale of insecticides, disinfectants, and sanitizers, detergents and cleaning compounds, automotive chemicals, and waxes, polishes, and floor finishes for household, institutional, and industrial uses. A significant number of these products have pesticidal claims and are, therefore, subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act as amended (FIFRA).

Specifically, CSMA represents the nonagricultural pesticide industry, including disinfectants and sanitizers, home, lawn, and

garden insecticides and a wide variety of other pesticides for home, industrial, and institutional use. We are here today to advise the subcommittee of our firm commitment to accept the language of Section 11 of H.R. 5203 amending section 24(a) of FIFRA, and respectfully urge the subcommittee to proceed expeditiously to markup.

First, I will discuss the background of section 24(a).

Mr. Chairman, this is the fourth occasion on which we have testified concerning the amendments to FIFRA. During these hearings, we have established beyond any doubt that first the State of California misused the regulatory process by demanding, usually without justification, in at least 85 percent of all State registration applications that registrants generate additional data beyond that imposed by EPA.

Second, the testimony showed that the administrative processing of applications was almost nonexistent resulting in unnecessary and unfair registration delays, often in excess of 500 days. I can tell you that there has been some progress. It's usually around 400 days now average. These regulatory delays have caused the industry to be shut out from the marketplace and have deprived consumers of the availability of safe and effective pesticide products.

In addition, our testimony clearly established a trend in several other States to introduce legislation or promulgate regulations calling for similar data requirements or imposition of duplicative and unnecessary registration burdens upon applicants. I'm going to name those States for the record once again. They are New York, Massachusetts, Maine, and West Virginia, and now Florida.

During this legislative process, we spoke to many constituent bodies including industry, user groups, consumer groups, State and Federal regulatory agencies, as well as Federal and State legislators concerning these State registration problems. All of these individuals without exception have expressed concern and some were dismayed over the problems typified by the California situation. CSMA was encouraged however to seek a compromise that would alleviate the registration problems while still preserving a State's authority to regulate pesticides.

The original section 24(a) amendment language called for a State to have a validated test or other significant evidence prior to requiring an applicant to submit additional information to the State for a review. While there was considerable support for this concept, the subcommittee suggested an alternative approach, that is, having EPA overview a State's data request. After considerable discussion within CSMA, our membership, in an effort to compromise, agreed to the concept of EPA oversight.

The State of California and a few other organizations opposed this concept, or any other for that matter, continually citing examples of agricultural pesticide considerations claimed to be unique to States. The concept that was finally worked out and agreed to by most parties including the Environmental Protection Agency staff eliminates this objection by recognizing that States may have special local concerns which should be considered on an individual basis.

Thus, for special local concerns pertaining to agricultural problems, there is no EPA overview, and the State is free to prohibit

sale, require additional data, and impose other requirements it feels are necessary to assure that the pesticide will be safe and effective under the unique conditions existing within a particular State.

In the case of a special local concern which does not pertain to an agricultural use, there is an EPA review to make sure that the data request is not arbitrary or capricious. State data requests for reasons other than a special local concern are likewise subject to EPA review for both agricultural and nonagricultural products to insure that such data requests are not arbitrary or capricious.

This review will result in selective and reasoned data requests by States and will therefore discourage unnecessary and unfounded data requests thereby significantly streamlining the registration process for the large majority of applications.

Let us be very clear about what the current amendment to section 24(a) does and does not say. First, the current language of section 24(a) remains intact and provides that the State may regulate the sale or use of any federally registered pesticide or device in the State to the extent that such regulation does not permit any sale or use prohibited by FIFRA. The new language in H.R. 5203 does not preempt the State's authority. It does not prohibit the State from banning a product or denying a registration. This amendment to section 24(a) is directed solely to instances where the State requests additional data and to the timely processing of applications for State registrations.

I turn now to the opposition against section 24(a) amendments.

Let me emphasize that the current section 24(a) amendment as contained in H.R. 5203 has the support of virtually every industry trade group, several States, and various grower groups, including the California Farm Bureau. In addition, the American Farm Bureau Federation here in Washington, after having analyzed fully the amendment to section 24(a), has in a letter to the Chairman removed its objections.

From the very beginning, CSMA sought participation of all parties in arriving at a reasonable compromise to solve the State registration problems. Virtually all parties recognized the existence of these problems. Some, however, have merely opposed any change while offering no constructive alternatives.

At one time or another, they have raised every possible objection. It has been argued that the amendment would saddle EPA with numerous data reviews, would increase the Agency's administrative costs, would spawn litigation, and would create yet another layer of bureaucracy.

These arguments do not hold up under careful scrutiny. EPA will not spend an inordinate amount of time sifting through State data requests. This was even corroborated earlier in the testimony this morning. There is no EPA overview, and hence no EPA involvement, in the area that seems to concern the States the most—special local concerns for agricultural products.

With respect to special local concerns that pertain to nonagricultural products, such as a toilet bowl cleaner or other disinfectants, it is very difficult to envision a local concern for such a product. But if one does exist, EPA would act merely to insure that a data request is not arbitrary or capricious.

With respect to data requests not subject to a special local concern, this amendment will merely direct that the States have a reason for requesting the additional data.

We submit, therefore, that forecasts of numerous data reviews by EPA are greatly exaggerated. Where there are few data reviews, it follows there will be no major increase in the Agency's administrative costs, the number of lawsuits or bureaucratic involvement.

One further point with regard to potential lawsuits involving EPA: the only time that a decision by EPA is reviewable in court is when that EPA decision overrules or modifies a State's special local concern data request—not the finding of a special local concern but the data request. Such suit, it should be emphasized, can be initiated only by the State, not industry.

As the substantive issues were one by one resolved in the present section 24(a) amendment, those in opposition were left with no more than a specious States' rights philosophical argument. This approach is reflected in the charge that the compromise language, "jeopardizes the ability of State pesticide agencies to discharge their responsibilities for public health, safety and environmental protection * * *". This statement distorts the provisions of the compromise worked out for section 24.

As we have already noted, the current language of section 24(a) remains intact and provides that the State may regulate the sale or use of any federally registered pesticide or device in the State to the extent that such regulation does not permit any sale or use prohibited by FIFRA.

The new amendment to section 24(a), as part of H.R. 5203, does not jeopardize the ability of State agencies to properly discharge their responsibilities but is intended to insure that the States act responsibly in making additional data requests.

In conclusion, CSMA believes that the compromise as contained in H.R. 5203 will move toward eliminating the two basic problems that now exist, that is, long registration delays and unnecessary data generation requests. To do otherwise will increasingly impose economic hardship upon the pesticide industry and deprive consumers of safe and effective pesticides needed to control pests which disrupt our economy and reduce the quality of our lives. The compromise leaves intact the State's authority to regulate the sale or use of a pesticide. At the same time, it also establishes an orderly procedure for reasonable data requests and timely registration by the States.

Though certainly not in agreement with all provisions, CSMA accepted the compromise in good faith and has worked diligently for its passage. We continue to fulfill this obligation, both to our membership and to this subcommittee, and we respectfully urge that the subcommittee include in total section 11 of H.R. 5203 to amend section 24 of the Federal Insecticide, Fungicide, and Rodenticide Act in the bill reported out.

Thank you, Mr. Chairman. I will be pleased to answer any questions.

Mr. BROWN. Thank you very much, Mr. Engel. You have made an excellent statement. Mr. Wampler?

Mr. WAMPLER. I also want to join the chairman in thanking you for your testimony here this morning, Mr. Engel. I want to thank

you for your continued efforts to try to resolve some of the very difficult questions that are now before the subcommittee.

You were present in the chamber earlier this morning when Mr. Grant, the executive secretary of the National Association of the State Departments of Agriculture indicated his organization's continued opposition to section 24(a), the amendment included in the bill before us.

I assume you also heard Mr. Grant testify that they were continuing to try to communicate, discuss, and hopefully to reach some resolution of this very difficult question.

You indicated in your statement that indeed during this legislative process your organization had worked with a number of user groups, interest groups, consumer groups, regulatory agencies and others in trying to resolve this question.

In your efforts to try to work out any differences that might exist with NASDA, have they been successful and what do you feel the hopes of resolving those differences might be?

Mr. ENGEL. Mr. Wampler, I do not believe anything will be resolved without Federal legislation. It is a Federal issue. It is a Federal responsibility. As well intentioned as NASDA as an organization is, I do not believe that they can be successful in solving this problem.

I must tell you that at their Boston meeting we had staff at that meeting making a presentation and trying to work with that organization to reach a compromise effort. That organization individually, as you speak to the membership individually, in many cases, are very, very concerned and do understand the problem but as an organization have stood on their position from day one that they want no change.

It is extremely difficult to compromise with an organization that is inflexible.

Mr. WAMPLER. As you probably know from the very outset of these hearings, I expressed some genuine concern. I find myself in a very unusual position in that I traditionally have been an advocate of States rights because I honestly feel that in most cases States are able to address problems of this type more appropriately perhaps than a Federal agency can. But this is going to be one of the real difficult questions that we are going to have to resolve right here, among others. But I do want to thank you for what your organization has done in trying to resolve this and in trying to get some compromise position that would be acceptable to all concerned and yet addressed itself to what is becoming a matter of increasing concern to this subcommittee and others that are affected by this problem.

Thank you for your response to my question.

Mr. BROWN. Mr. Wampler has indicated the problem that I'm sure many Congressmen have about confronting the issue of States rights here.

While I am not a constitutional lawyer, I should point out that we do have limitations on States rights required, specifically applicable in this case when there is an undue burden on interstate commerce. I presume this would be the case made by the industry with regard to the possibility of unnecessarily having a burdensome regulation at the State level.

Mr. Fithian?

Mr. FITHIAN. Mr. Chairman, I want to commend Dr. Engel. He's becoming more forceful in his old age. Maybe I should say as he gets more experience.

Let me underscore what I believe your initial thrust was and that is to try to get the message across that your effort distinguishes between agriculture and nonagriculture used pesticides.

If we could take this analogy away from this aspect of the regulatory arm of the Government and apply it somewhere else where we are not quite so contentious over this particular bill, then I think it is not too dissimilar when we pass or rather we establish or the Government promulgates a regulation which falls upon some very large sector of the society like General Motors in the Clean Air Act.

That may not in fact be such a burden for them to legally and otherwise comply. When you break it down to the use of small insecticides in something that technically falls in the jurisdiction of the EPA, that is quite different from a pesticide that was going to be used across the land on soybeans for example or whatever.

So, all regulations do not fall evenly, depending upon the size of their use, and while that regulation may not impair General Motors with a similar regulation impacting upon a small firm makes it prohibitive for that firm to do business.

What we may see here is that unless we can figure out some way of distinguishing between categories of uses both in terms of danger to health and to the environment which we are charged with the responsibility of doing and on the other hand the difference in the economic impact, then we will soon crowd out many. It is very much like the agricultural side of this where you get into a special crop use. They are not going to do the research if it is just for a small extension of use pattern that may be vitally needed in the growing of pears, let's say, but would not withstand research costs as if you were dealing with corn or some large crop.

So, I think we do have to, for a matter of reason and a rational approach to this, begin to distinguish between the categories of things that are sort of scooped up as it were in the net of FIFRA.

I commend you for your argument. I do not know how we will make out through this process, but I would urge the members of the Subcommittee to focus on Dr. Engel's principal point which was to distinguish between nonagricultural and agricultural pesticides. It is that which is now the only thing relevant in section 24. We are not now dealing with all the other things that have sometimes caused so much contention in this hearing room.

We are really down to nonagricultural used pesticides in this particular instance in this section of the law. I think we probably should try very hard to keep a focus on that point.

I have no questions for Dr. Engel, but I want to commend him for his statement. Thank you, Mr. Chairman.

Mr. BROWN. Thank you, Mr. Fithian. I want to thank you for your cogent explanation of the impact.

Mr. Panetta?

Mr. PANETTA. Thank you, Mr. Chairman.

Dr. Engel, if there were no change at all provided and simply a reauthorization of the act as it exists now, what would be the pos-

ture of the industry and what would be the impact on the industry?

Mr. ENGEL. We would be opposed to it because we feel that we have indeed in good faith compromised our position to the point where it is fair and equitable to all, including the States and the industry and the Government. We would definitely be opposed to that position.

As for an effect, it would have a major effect. In our judgment, it would trigger and show indeed the light for other States to move quickly into the arena. They are moving there now but I say quickly into the arena and disrupt totally the national marketing efforts of many companies.

Mr. PANETTA. If no changes were made, industry would continue to contest or litigate issues relating to requests for information and so on. Right? I assume that the present situation would not change.

Mr. ENGEL. I cannot respond to that as to what individual companies would do.

Mr. PANETTA. What would you anticipate? You have enough experience.

Mr. ENGEL. I suspect there would be some litigation, but it's extremely difficult to litigate piece by piece or registration by registration. The costs are enormous. I think a major effect would end up being that they drive the products out of the States.

You must recognize litigation can take years as well.

Mr. PANETTA. Yes.

I don't know whether EPA is for or against this but let's assume that they're opposed to the provision. In considering the situation at EPA in terms of manpower, does that concern you at all if EPA were opposed?

Mr. ENGEL. No, it does not. If I could guess, I suspect that EPA would probably say that they do not want to have the responsibility of being in the middle, but on the one hand they understand that there is a problem and that they are concerned about it.

There is a Federal role to play—a Federal leadership role to play—particularly with standards.

On the other hand, they might say that they are not certain that they should go against this "specious argument of States' rights."

While this administration admittedly is directed toward the policy of deregulation and a shift to more regulatory responsibility to the State level, the administration is keenly aware that there are areas of regulation that require Federal responsibility and coordination.

In the areas that affect interstate commerce and technical standards which have a national if not international significance are areas that require Federal leadership.

To be very candid with you, if every State did their own separate scientific evaluation which led to a decision not to allow the use of an EPA registered pesticide or to require conditions for use different from that permitted by EPA, this kind of divergence in registration practice would lead inevitably to serious problems that would adversely affect the public.

This kind of divergence—indeed if each State conducted its own scientific evaluation for registration there would be no need for EPA to do the same.

FIFRA would be meaningless. If the States could, by the nature of the system, continually overrule the Federal standards, then it would be meaningless.

Mr. PANETTA. It's an interesting situation that we are in. In effect, industry normally argues against increasing Federal regulation and is in favor of deregulation in these areas.

I understand your arguments and I sympathize with those arguments. I think in fact there is a national responsibility, and there's no question about that.

However, what concerns me is that perhaps in this administration the policies may be such that they are implemented with some regard for the industry, but perhaps in future administrations a more aggressive EPA administrator might not do it with that kind of sensitivity. That is the gamble you take. Law is not something that changes from administration to administration. In fact it is something that will be ongoing and that will be pursued, depending on the sensitivities of the administrator and the administration that is in power at that time. You understand that that would be the situation. I think that is important for all of us to understand.

Mr. ENGEL. We indeed do understand that. There is no authority other than EPA federally where such expertise lies other than to have it in 50 States.

There is no scientific expertise elsewhere except in EPA. We accept that not just this administration but we except it totally.

We recognize that there must be some overseer in this process.

As Mr. Fithian indicated, however, this is a nonagricultural pesticide issue. We are not overseeing the other side. We are overseeing a nonagricultural use of pesticides.

It is a compromise. It is an effective one. We do not like everything about it to be very candid about it with you, but I never did. However, we are supporting it because we think it is the right thing to do to move this bill through the legislative process. We think it will work.

It's as simple as that.

Mr. PANETTA. Thank you.

Mr. BROWN. Mr. Fithian?

Mr. FITHIAN. I am struck at the sharply differing positions that you and Mr. Grant have taken this morning as to whether or not it is a problem with a single State or whether it is a growing problem that we may have to wrestle with again and again in the committee.

Mr. Chairman, I'm not sure how we harmonize these two points of view.

You talked about three or four States. Would you take 1 minute more, Dr. Engel, and specify what those additional States are doing that would lead you to the conclusion that in fact there is more of this on the way than we've already seen?

Mr. ENGEL. Massachusetts last year introduced a bill that would require submission of duplicative EPA data. It is very truly the same as the California bill and frankly goes a little further.

It would require additional data as well.

That bill was defeated but it is up again. New York has attempted to require environmental impact statements prior to registration. You recognize an environmental impact statement relates to

the same data. This is in addition to registering the pesticide and you have to indeed go through the hoop of requiring an environmental impact statement and using that data again.

Several months ago I think we provided this data to the subcommittee now that I think about it. Would you like for us to submit that again?

Mr. FITHIAN. No, I wanted to hear this today while we have these two different views.

Mr. ENGEL. Let me name another State. Maine has attempted and is currently attempting a third category of restricted products. Oregon would extend pesticide regulatory authority, including existing and additional data, to substate levels of government—not just State but substate levels of government. That bill is in existence.

Mr. FITHIAN. As we are drafting and working on section 24, there really is not any very specific prohibition against States taking additional action. My question then is this. Would these three or four or five States now moving in the direction of the California experience be in fact denied the opportunity to move in that direction under this bill?

Mr. ENGEL. No. We have stated up front that this bill gives the States the right to regulate the sale and use of a pesticide. It does not change section 24(a) the way it is today. It just adds a procedure for collecting data responsibly and gives EPA an overview with regard to certain data as regards nonagricultural pesticides. EPA can determine that it could be arbitrary or capricious to request and deny it or modify the request by saying, "Look, I have that data and I will supply it instead of the company doing it again because this already exists in our files."

EPA could say, "We do not think the data would do anything for you and so we overrule it."

They cannot do that for agricultural pesticides. This is for non-agricultural pesticides.

It is really a little notice that says, "Think before you act."

Mr. FITHIAN. Thank you.

Mr. BROWN. Mr. Panetta?

Mr. PANETTA. I apologize to the chairman because I think this has been answered before, but I would like for you to present to me in a few sentences the rationale as to why there needs to be protection of information to begin with. Why should there not just be public information for everybody regardless?

Mr. ENGEL. I'm not questioning that. We are not suggesting that we're trying to prevent the data from being seen.

Mr. PANETTA. There's a process of controlling that information flow. I am asking what is the basic problem.

Mr. ENGEL. It is registration. We are seeking to register our products that are somewhat innocuous. We are talking about things like disinfectants and toilet bowl cleaners and things like that.

We are seeking to get out of the burden of producing excess data that is not needed. It could be available at EPA. We have gone through the process of registering a product at EPA and providing the data and now the States want that data and they can't get that data now. But it wants more and more and more without reason.

We are simply saying that if they want more data and if they have a special local concern then they should tell us. If they have that special local concern and the data is relevant, then we have an obligation to provide it.

Mr. PANETTA. It goes to the issue then of delaying an impact because of having to respond to many, many different requests for the same information. Is that right? Is that the basic problem? It's not a question of trade secrets?

Mr. ENGEL. No. Long registration delays and unnecessary data generation requests.

Mr. PANETTA. Thank you and thank you, Mr. Chairman.

Mr. BROWN. Dr. Engel, we want to thank you and your two colleagues for your testimony here today.

We next have a panel of three witnesses, Mr. Kirk Johnson, Center for Science in the Public Interest; and Mr. Stephen Brobeck, Consumer Federation of America; and Mr. Clyde Shorey, March of Dimes, New York. We welcome all of you gentlemen to the table. Mr. Johnson?

STATEMENT OF KIRK A. JOHNSON, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Mr. JOHNSON. Mr. Chairman and members of the subcommittee, my name is Kirk Johnson. I am assistant director of the environment and behavior program at the Center for Science in the Public Interest in Washington, D.C. Center for Science in the Public Interest is a non-profit organization involved in issues regarding health, nutrition, and the safety of food. We represent a diverse group of over 30,000 nutritionists, educators, physicians, students, housewives, and other consumers.

I deeply appreciate the chance to comment on the question of proper disclosure of health and safety data. To save time, I'd like to summarize my statement and ask that the full statement be entered into the record.

We are well aware of the importance of weighing the costs and benefits of disclosing these data. The public ought to have easy access to information about chemicals that can affect their health. At the same time, corporations should be allowed to protect trade secrets from their competitors. This delicate balancing of interests is embodied under section 10 of FIFRA. Under the pending legislation before you, this balance is destroyed.

Under FIFRA, manufacturers can protect trade secrets, and any citizen can obtain health and safety data by writing EPA. Under H.R. 5023, manufacturers can still protect their trade secrets, yet citizens can easily be denied access to important health and safety data.

We believe there are many advantages to full disclosure of health and safety data. I'd like to address two of them here.

The first is that full disclosure would help improve the effectiveness of the Environmental Protection Agency. Test data are often scientifically inconclusive, permitting different scientists to arrive at different interpretations of the same data. History is replete with incidents where manufacturers, because of their financial interest in obtaining agency approval for a product, reported and de-

signed studies in a way that makes their products appear in the most favorable light. Traditionally, the scientific community minimizes these biases by subjecting test results to peer review by other scientists. If, however, disclosure of data submitted to agencies is limited, as in the amendments pending before you, the data may never enter normal peer review channels. As a result, agency scientists may be more prone to misinterpret the data that is submitted.

We recently investigated one example of EPA decisionmaking where we believe such errors in judgment were made. The case involves the pesticide carbaryl, which is manufactured by Union Carbide Corp. under the trade name "Sevin." In 1975, rising concern about the health effects of carbaryl prompted EPA to place the pesticide under consideration for a thorough review, a review that could have ended with EPA taking the pesticide off the market. For 5 years, EPA collected health and safety data on carbaryl. But suddenly in December 1980, EPA dropped its review. This gave the pesticide an implied clean bill of health and cleared the way for the pesticide to be used to control gypsy moths across the Nation.

Why was carbaryl dropped from review? EPA spokesmen say "the weight of the evidence" suggested carbaryl is safe. Yet CSPI has learned that Union Carbide representatives met repeatedly with EPA staffers throughout the 5 years of EPA's review, sometimes submitting lengthy documentation attesting to the alleged safety of the pesticide.

One former EPA project manager for carbaryl told CSPI, "Union Carbide kept coming to us saying 'We're having problems with our overseas sales,' reminding us that carbaryl had been banned in Egypt just because we had it under consideration for review here. They kept pressing us to make up our minds one way or the other, hopefully in Union Carbide's favor."

This repeated lobbying apparently paid off. EPA canceled its review, despite the strong objections of a senior agency scientist who wrote, in a draft memo obtained by CSPI, that the decision does not appear to be justified by scientific studies. This draft memo also revealed that EPA allowed Union Carbide to review and ostensibly to comment on, the document announcing EPA's decision to drop carbaryl before the document was made public. It is ironic that although Union Carbide was allowed to review the document before publication, other EPA offices were not. In the words of the memo: "If there was time for Union Carbide to examine the document, there should have been time for the Agency to review it too."

Mr. Chairman, I have a copy of this draft memo. Pertinent names have been whited out to protect employees who are still at EPA. I ask that it be entered into the record.

We believe that the carbaryl case illustrates the risk that EPA runs of becoming captive to a company that Congress has instructed it to regulate. This can happen when an agency's decisions about health and safety data are made in isolation, outside of normal peer review channels. Giving everyone open access to these data will allow the data to be interpreted by the entire scientific community, not just industry scientists and a handful of agency decisionmakers. The result will likely be more impartial decisions.

The second advantage of full disclosure of health and safety data is that it will allow citizens to make more informed choices about pesticide use. We recently telephoned a sampling of our members and other consumers to hear their reaction to the proposed section 10 amendments.

Many food store owners were worried that the amendments would block the flow of information about pesticides to their customers. Harrison Drinkwater, who runs a food co-op store in Manchester, N.H., routinely supplies information on pesticides to his customers. Mr. Drinkwater told us his store would be severely handicapped by the proposal. Mr. Drinkwater has obtained valuable health and safety data under the Freedom of Information Act from EPA's Boston office and he fears that these amendments would hamper the flexibility of the Government in responding to citizen requests.

Mary Teresa Gray, from the New Brighton, Minn. Co-Op pointed out that the amendments seem contrary to the Reagan administration's goal of streamlining, rather than building, a bureaucracy. Diana Rainwater from Puget & Consumer's Co-op in Seattle said the amendments would construct a system so cumbersome that only the most diehard consumers would succeed in getting the information they need. Gary Osteraas, a college nutrition teacher, doubted that small farmers and food distributors interested in health and safety data would take the extra step to obtain it that the amendments would require. The hardship and frustration these amendments would pose are perhaps best summed up by Mattie Perelman, a housewife from upstate New York, who remarked "Who on earth would have the patience?"

These are but a few of the comments that citizens have registered in opposition to H.R. 5203. I submit that this is the very tip of the consumer opinion iceberg.

To summarize, Center for Science in the Public Interest supports the policy contained in FIFRA that data should be made readily available to all members of the public. We oppose the present amendments, which restrict access to data. We believe any amendments to the act should contain measures other than those in section 10 of H.R. 5203 to protect corporate trade secrets.

As an addendum to my testimony, I'd like to submit an open letter to you and Senator Luger from over 100 concerned scientists and others who attended the American Association for the Advancement of Science annual meeting in Washington, D.C. These individuals ask that this subcommittee not restrict access to health and safety data. I ask that this be included in the record.

Thank you.

[The attachments to the statement are held in the subcommittee file.]

Mr. BROWN. Mr. Johnson, I want to thank you very much for your testimony.

[The prepared statement of Mr. Johnson appears at the conclusion of the hearing.]

Mr. BROWN. Mr. Brobeck, will you please proceed.

**STATEMENT OF STEPHEN BROBECK, EXECUTIVE DIRECTOR,
CONSUMER FEDERATION OF AMERICA**

Mr. BROBECK. Thank you very much, Mr. Chairman. I am Stephen Brobeck, executive director of the Consumer Federation of America. On behalf of our 220 member organizations and their 35 million members, the Consumer Federation of America urges you to reject the changes proposed in the H.R. 5203 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act.

It is our belief that these changes would erode protections now enjoyed by American consumers. Specifically, we believe they would restrict the public's ability to learn the health and safety effects of pesticides and would make it difficult for State and local jurisdictions to address the distinctive problems of their areas.

Mr. Chairman, I am pleased that the members of the subcommittee have heard from a broad range of persons affected by pesticide dangers—chemical workers, pesticide applicators, growers and agricultural workers, consumers and citizens who enjoy the environment—since death and disabling injury to occupational and accidental exposure strike further than the farm.

Figures from the National Clearinghouse for the Poison Control Centers graphically illustrate the costs to U.S. consumers from pesticide poisonings. Indeed, these figures are startling since, according to the Clearinghouse, such statistics represent only 10 percent of the actual chemical poisonings reported to the Poison Control Centers each year. Thus, the 9,000 sample reports received by the Clearinghouse in 1978 represent only a fraction of the larger numbers of Americans who suffered pesticide exposure that year.

Black Flag Roach and Ant Poison: 166 poisonings, 97 children. Echols Ant and Waterbug Killer: 234 poisonings, 205 children. Harris Famous Roach Tablet: 122 poisonings, 108 children. X-14 Instant Mildew Remover: 73 poisonings, 27 children. Chlordane Use for Termites: 244 poisonings, 60 children.

Such illustrations can be made for numerous years, from numerous sources, and for numerous pesticide products. Neither insecticides, herbicides nor rodenticides omit the consumer from its victims. Pesticide products may be used in greater poundage in agriculture but I suggest that total users may be greatest in the household and garden market. Congress has strong responsibilities to keep consumer protections under FIFRA in place.

Congress struck a fair and equitable balance in 1978 when it provided the American consumer with access to health and safety studies submitted to the Environmental Protection Agency by pesticide registrants. Congress considered that disclosure might reduce the incentives for new product research and development by preventing companies from fully recouping the high costs of generating the required test data and make it easier for competitors to duplicate and license breakthroughs. Yet Congress concluded that the societal costs of nondisclosure were greater. An ingredient in that decision was that nondisclosure would deny farm and nonfarm consumers the opportunity to make fully informed product-use decisions.

Members of the public who must make decisions about the use of products receiving the Environmental Protection Agency (EPA) ap-

proval have a legitimate interest in the full health effects of these products. Indeed, information of this sort is essential to the efficient operation of a free market economy.

The EPA of course strives to protect consumer safety but does so via very broad risk-benefit determinations for classes of consumers. Since a licensed chemical may harm certain individuals more than it helps them, individual consumers should have information available to them to make decisions balancing risks and benefits.

Critics have argued that consumers are not capable of making complex judgments. Yet this argument is based on a gross underestimate of people's intelligence, commonsense, and awareness of their limitations. It is also antidemocratic, Orwellian in its implications for the role of Government. There are certain risks that must be taken in a democracy and market economy, and disclosure of health-related information is one of the least of these.

The Consumer Federation of America recognizes that few consumers would take the time to read the voluminous health and safety data submitted to the EPA before making purchasing decisions. Scientists, product-testing organizations, and consumer reports however would and could use this information to inform the public of potential or relative risks.

Probably the most widely read periodical of consumer material is *Consumer Reports*, published by the Consumers Union. Interestingly, that magazine's 1979 report on the household insecticide diazinon was impeded because the extent to which it was contaminated by a toxic impurity was considered by the EPA to be proprietary and thus confidential information.

I reiterate that it is a fundamental right in a free enterprise system that consumers be informed. Congress should not impede public access to this important information.

The current amendments in H.R. 5203 to section 10 do impede public access.

First, Freedom of Information Act access now permits consumers and consumer representatives to obtain health and safety data through written requests to the Agency under established time guidelines. H.R. 5203 contemplates creation of an untried, untested system of library reading rooms with approved mail privileges for certain individuals. This occurs at a time when many regional libraries within the EPA system are facing severe budget cuts creating problems ranging from sudden staff reduction to the closing of region II's library to the public.

Second, H.R. 5203 unrealistically alters the review of data obtained through this bureaucratic maze. Who may review the data is subject to both the EPA and the chemical industry's background check. What data can be summarized and that which may be copied verbatim is confused: With whom may an academic researcher share borrowed copies of health and safety studies? Must each reader be screened by the EPA Administrator and by each company whose data the research seeks to scrutinize? Simply speaking, the process becomes unwieldy.

Third, to what use may this data be used? If the data can be used in an adjudicatory hearing such as suspension and cancellation, may it be used in a notice and comment rulemaking proceeding? Will the ability of a consumer-oriented magazine to quote from a

submitted registrant's chronic effects study be greatly inhibited by the proposed disclosure penalties?

Fourth, the penalties, too, do not offer industry what it seeks in preventing corporate theft of health and safety provisions. They envision a series of penalties which are harsher to Government and public disclosure than to corporations who violate the act.

Under H.R. 5203, the possibility that a consumer requesting health and safety data might negligently allow it to fall into the hands of a foreign competitor acts as a significant disincentive to those who may desire to examine the study. While it is clearly appropriate to punish someone who abuses this right for commercial advantage, it seems less justifiable to threaten to punish someone criminally when that person is merely negligent.

The intent of industry seems to be to make the public's route to obtaining health and safety data so cumbersome, complicated, and costly that citizens will be discouraged. At best it is, as I believe Mr. Thompson characterized it, an "antitechnology" amendment.

These are indeed very substantial changes. We believe that they would deny meaningful access to health and safety data. They would also deny a meaningful review of the data and subject the new section 10 provisions to endless litigation, essentially removing the provision from the statute. I would submit that this is contrary to both the proposed reasons for the current change and goes further than is necessary to harmonize the legitimate interest on both sides.

The National Agricultural Chemicals Association has not come forward with any hard evidence to suggest that drastic amendments to FIFRA are needed. Concern for competitive harm is one shared by the Consumer Federation of America. Consumer organizations are supportive of provisions which assure varying product lines, continued research and development, and increased innovation. But current protections and proposed section 3 changes protect domestic markets.

Instead, the chemical industry bases its concern on loss of foreign markets to foreign competition. This argument, is dubious.

First, there is no reason to believe that foreign data requirements correspond to U.S. requirements. Foreign markets would presumably require much less testing where case summaries or even much less could register a product.

Second, there is some patent protection, however good, which will protect products that are already patented.

Third, American firms who have developed a product will enjoy a lead time and an advantage as being first on the market. It is an economic matter that the first on the market gains an advantage that he may never lose as long as the market exists.

I turn now to State right to protect consumers in excess of the Federal law.

In 1972 Congress wrote the basic structure of FIFRA where the issue of State authority was settled balancing industry concerns for uniformity and State demands to protect historic State police power. Some States had developed full-scale pesticide regulatory programs well in advance of the Federal law. The 1972 compromise was simple, clear, and has worked well since that time.

Section 24 of the current law authorizes States to regulate the sale and use of pesticides with but two limitations: States cannot be less restrictive than the Federal Government, and States cannot change label and packaging. These provisions offer the American consumer minimum safety standards and a uniform labeling system. The amendments before you in H.R. 5203 attack a State's authority to regulate pesticides by a pernicious route: H.R. 5203 limits the power of the State to obtain information from product manufacturers.

Our criticisms are many. First, States are prevented in a practical sense from obtaining information from a company since H.R. 5203 allows companies to refuse State requests and send States to EPA to face time delays and disclosure regulation.

Second, H.R. 5203 distinguishes between special local concerns where information requested is of a State boundary nature and where there lies a Federal interest where presumably data is applicable to a larger geographic subdivision. Thus data on residues on crops in California's unique weather would fall into a "special local concern" while a State request for metabolic pathway studies and indoor exposure data would not be unique to the State. Yet such a system removes the protections to the consumer who, as case examples demonstrate, have benefited from such State action.

For instance, the State of California now requests health and safety data of rodenticide registrants on the metabolic pathways of their products. This requirement results from the accidental poisoning of young children who ingested rat bait sold to consumers within that State. This pesticide kills insulin-producing cells in the pancreas resulting in severe diabetes. Unfortunately, the mode of action is irreversible after ingestion.

This product had been registered for use by EPA without this data. Had this data been requested, perhaps the product would not have been marketed—most likely so in California. Instead as a result of several tragedies, a request for further data was made by State government which then canceled the product's use.

We at the Consumer Federation of America believe that residents of each State are due the additional protections offered by elected and appointed State officials. In many instances consumers across the Nation can benefit from the wisdom and experience of each State represented on this subcommittee.

While I do not suggest that this particular instance of State regulatory action would be vetoed under the terms of H.R. 5203, I do believe that these provisions place a serious disincentive for States to instigate research and investigative time to identify problems consumers are suffering within their jurisdiction.

Given that EPA may overrule or modify a State request or send the State to some "comparable" data source and given that manufacturers may challenge State action in court before or after the EPA Administrator's review, States are presented with disincentives to expending very limited State resources on actions which will be subject to a troubling bureaucratic maze.

Moreover I am troubled by the arbitrary distinction in H.R. 5203 creating a distinction between agricultural and nonagricultural pesticides. Consumers of household and garden pesticide specialties are seriously harmed by a distinction that creates additional hur-

dles for State regulatory agencies to go through to request data on products which are used by more Americans than commercial food pesticides. There is no sound policy rationale for this division based in science or economics or human health.

Home and garden use pesticides are responsible for most recorded poisonings, and States have been critical of EPA's poor record in regulating these consumer products. Let me suggest that American consumers are most harmed when public policy is formulated not by a sensible reliance on fact but on the political intensity of one narrow interest trade association.

In conclusion, I wish to briefly note that both sections 10 and 24 share several unattractive features. Both would give one Federal official, the EPA Administrator, the authority to make final decisions on certain critical issues that are not subject to judicial review. Both would also require more extensive and costly regulation by the Federal Government. And finally both would limit State authority at a time when budget cuts will not permit EPA to pick up the slack.

All this is of course no secret to pesticide manufacturers supporting revision of the law who, over the past decade, have advanced contradictory arguments in an effort to remove important safety protections.

Thank you.

Mr. BROWN. Thank you very much. Mr. Shorey.

STATEMENT OF CLYDE E. SHOREY, JR., VICE PRESIDENT, PUBLIC AFFAIRS, MARCH OF DIMES BIRTH DEFECTS FOUNDATION

Mr. SHOREY. I wish to thank the subcommittee for the opportunity to appear and state the deep concern of the March of Dimes about two proposed amendments to FIFRA.

The March of Dimes has as its major goal the prevention of birth defects and the birth of healthy babies. These objectives are carried out through a nationwide system of chapters in every community in the United States and by more than 1 million volunteers.

By a letter dated December 3, 1981, I set forth the views of the March of Dimes concerning proposals for amending sections 10(d) and 24(a) of the act. These views apply equally to H.R. 5203. We believe that these amendments seriously undermine the scientific review of the effects of pesticides which could cause birth defects and other reproductive health problems. We also believe that H.R. 5203 places unwarranted restrictions on States to protect the public under local conditions.

The disclosure restrictions proposed for section 10(d) through a complicated application and nonappealable review process, use of reading rooms, restrictions on copying and disclosure, and severe civil and criminal penalties will severely limit research by the scientific community into the mutagenic and teratogenic effects of pesticides to which the public may be exposed.

The March of Dimes is gravely concerned about the scope, level, and quality of research into the mutagenic and teratogenic effects of pesticides and other reproductive hazards. We have established our own special program of grants for scientific research on reproductive hazards in the workplace.

We also cosponsored a conference in January 1981 with EPA, CDC, OSHA, and the National Institute of Environmental Health Sciences to review the state of the art and establish, "Guidelines for Studies of Human Populations Exposed to Mutagenic and Reproductive Hazards." The "Guidelines" have now been published. I have a copy here available to the committee if they would like to review it.

Mr. BROWN. I would like to have a copy of that for the committee files. Without objection, it will be included in them.

Mr. SHOREY. As a result of that conference the scientific community has organized itself, after the most extensive review of the current state of the art, for serious research into this most difficult area.

In order for this research to be effective and as fully comprehensive as possible the availability of test results filed with EPA is essential. Under the proposed amendments genetic defect data, exposure incidence data, epidemiologic studies, medical treatment descriptions, and other public health material will not be available for review or if so only under severe restrictions. This data is absolutely essential in order to evaluate the conclusions concerning the hazardous effects of the chemicals involved. This data must be freely available to the entire scientific community for the broadest possible review. It is even possible that such data would not be reviewed and discussed at a conference, such as the one held a year ago, because someone might attend who was not entitled to the data.

Furthermore, this broad availability of the data tends to stimulate new research on this or a related product or chemical. This is one major way new scientific discoveries are made.

It was because of the less than adequate testing and data development at Love Canal that the conference to develop the "Guidelines" was held a year ago. The "Guidelines" not only point the direction for new research in this vital area, but they also establish benchmarks for evaluating test data and conclusions. This can only be effective if the health and safety data for new and existing pesticides and other reproductive hazards is freely available to the public. Any reduction in the freedom to review the health and safety data filed with EPA for pesticides is hazardous, not only to the present population but especially to all future generations.

The March of Dimes also opposes an amendment to section 24(a) to eliminate the right of States to set stricter standards than those established by the Federal Government. Local conditions may require special action not recognized by the minimal requirements of FIFRA. To properly protect the public from exposure to conditions which can affect the outcome of pregnancy, as well as other health hazards, States must be able to provide for unique situations.

The March of Dimes therefore urges the subcommittee not to amend sections 10(d) and 24(a) of FIFRA.

We wish to thank the subcommittee for the opportunity to present our views.

Mr. BROWN. Thank you very much for your testimony. Mr. Panetta.

Mr. PANETTA. Mr. Johnson, in your testimony you pointed out also the concerns related to the violations that would take place in

terms of the industry and the trademarks of the particular product involved, as opposed to health and safety data.

Understanding that, how would you control information in this context? How do you have totally open access to all the health and safety data and not be concerned about the other aspect?

Mr. JOHNSON. Our position is that the requirements that are contained in FIFRA as it now stands which do allow manufacturers to designate what information they submit to EPA as a registrant are satisfactory.

In other words if a manufacturer wants to designate some of that information as confidential or trade secret information, then he or she can and that is fine. But our concern is that limiting the access to any other individual of information that can relate to that person's health, that kind of move is irresponsible and should not take place.

Mr. PANETTA. That's a point. I'm not a scientist. I'm not that familiar with the technicalities involved here, but as an attorney I think I could probably argue that almost every bit of data that is filed by industry could relate to the health and safety issue. Isn't that legitimate?

Mr. JOHNSON. I'm not a lawyer. [Laughter.]

Mr. PANETTA. As a scientist, isn't it a fact that almost every bit of data that is involved in the development of pesticides could be argued that it relates to health and safety?

Mr. JOHNSON. Yes, it's arguable but I think it's important also to draw a line between information—there's a line drawn between information that can clearly be separated from the bulk of data that is submitted to EPA and which gives no clue to a manufacturer's operations and the information that does.

Mr. PANETTA. I don't understand that. Maybe you understand that better than I do, but it would seem to me that any information that relates to a formula and the ingredients that go into a formula would be absolutely essential to look at in terms of health and safety.

Mr. JOHNSON. That could be argued, but I also think it could be argued that information about the health effects of the pesticide are different from information talking about how a pesticide is made and what ingredients may be in a pesticide.

Mr. PANETTA. I don't see the distinction. How can you possibly determine health impact unless you know exactly what the ingredients are that are contained in the formula?

Mr. JOHNSON. I think the members of CSPI would argue—I can only repeat. It is important for information that affects the health of consumers to be released.

If I'm exposed to a pesticide and I go to a doctor, it does not really matter to me exactly what chemical formulation is in that pesticide or how it is made or in what quantity it is made. What is important to me as a consumer is what it does to me. That's the information we're trying to get access of citizens and physicians and nutritionists to. I don't know if that answers your question.

Mr. PANETTA. These are very tough decisions. You are trying to balance two interests involved here. One is the health and safety factor and the other is, on the industry side, that having put time, and effort, and money into development of a pesticide, industry

wants to keep competitors from getting access to the exactly same formulas that they worked on.

That is the purpose. Thus is bred this piece of legislation to try to come up with some kind of balance.

All of the attacks to the legislation fail to come up with, it seems to me, any kind of legitimate alternative. You either open it up entirely or you have somebody try to control the access to the information.

How do you weigh those interests?

Mr. JOHNSON. Access to the information is controlled under FIFRA as it stands. We on the other hand would like to see the chemical industry come forth with concrete examples as to how access to information that has been supplied under FIFRA as it now stands has hurt a competitive advantage and has hurt their business.

Mr. PANETTA. In other words, you are asking whether there has been any impact in terms of information being released on the particular industry involved?

Mr. JOHNSON. We would like to see definitive information claiming or showing that this impact has been substantial, yes.

Mr. PANETTA. I'm not sure whether testimony has been presented to that affect or not, Mr. Chairman, but I'd be interested in seeing whether that in fact has been the case and whether testimony has been presented along those lines. This seems to be one of the key issues involved in what we're doing in this legislation.

Mr. BROWN. Our next witness might respond to that.

Mr. PANETTA. I thank Mr. Johnson.

Mr. BROWN. If there are no further questions, I want to thank all three of you for your testimony this morning.

Our next witness is Dr. Jack Early, president of National Agriculture Chemicals Association. He will be accompanied by Dr. Dale Wolf. We welcome both of you gentlemen here this morning.

STATEMENT OF JACK D. EARLY, PRESIDENT, NATIONAL AGRICULTURE CHEMICALS ASSOCIATION, ACCOMPANIED BY DALE E. WOLF, VICE PRESIDENT OF DU PONT CO.; CHAIRMAN OF THE BOARD OF DIRECTORS, NATIONAL AG-CHEM ASSOCIATION

Dr. EARLY. Thank you, Mr. Chairman, and good morning.

Mr. BROWN. We trust you are in fine form.

Dr. EARLY. I'm in excellent form, Mr. Chairman. I hope all the subcommittee is. We look forward to these monthly visits that we've had the last 6 months. I'm a little disappointed we have not made a little progress in spite of the tremendous effort you and I have both put into this program.

Mr. BROWN. We share that feeling.

Dr. EARLY. Mr. Chairman, as you know I am the president of National Agriculture Chemicals Association. I have with me this morning Dr. Dale E. Wolf, vice president of the Du Pont Co. and the chairman of the board of directors of the National Ag-Chem Association.

The National Agricultural Chemicals Association [NACA] is a nonprofit, trade organization of manufacturers and formulators of pest control products employed in agricultural production. NACA's

membership is composed of the companies which produce and sell virtually all of the technical crop protection materials—active ingredients—and a large percentage of the formulated products registered for use in the United States.

Mr. Chairman, in our testimony before this subcommittee last summer we recommended an amendment to section 10 of FIFRA built around the critical importance of innovation in our industry as it relates to productivity, farm income, exports, and the balance of payments.

We presented then what we still insist was a reasonable proposal designed to strike a workable balance between the need to protect industry confidential research, and test data including health, and safety data from unwarranted public and competitive disclosure, and the public's right to be informed concerning the risks, and benefits of crop protection chemicals.

In our testimony we recommended that industry data or summaries be available in a public reading room at EPA's office. We suggested that interested parties should be allowed to examine the data within the reading room, take notes on its contents, but should not be allowed to photocopy or remove any part of a data package.

Why did we take this position? Primarily because the present section 10 is anti-innovational. It allows EPA to put industry's data on the street 30 days after receipt.

The research and development of new agricultural chemicals is one of the few areas of innovation where the United States is still a leader. We are still able to feed ourselves and export some \$40 billion annually in agricultural commodities, due in large measure to the availability of modern pest control chemicals.

Data contained in a typical registration package for a new agricultural chemical represents an investment of \$20 to \$25 million and 8 to 10 years of laboratory, field, and environmental testing. I believe we showed an example to this committee back last fall, Mr. Chairman. We brought a package of that information in some 12 feet high. It is high-risk type of research, often involving the screening and evaluation of 10,000 or more compounds for every one that is commercialized.

The data required by the Environmental Protection Agency [EPA] for product registration contains valuable research techniques, proprietary scientific methodologies, and product development information of great value to competitors. If this information were publicly disclosed, competitors could use it to obtain foreign pesticide registrations in those countries where patent law allows this, which is frequently the case. They could also use it in the United States or abroad to develop and produce competing products of the registrant.

The disclosure of American data undercuts the incentive to invest in research and innovation. It weakens our technological advantage which in turn weakens our agricultural production exports and economy. While appreciating the public's right to oversight, the innovation of American companies needs equal protection.

Again, we remain convinced that our original position of a secure reading room at EPA in Washington, without data leaving it, is the right one. In fact, we would even go so far as to allow this informa-

tion to be made available in one of the regional offices of EPA but always under the control of the Environmental Protection Agency.

During the months following the first FIFRA oversight hearing on June 16, 1981, the content of the proposed amendments to section 10 of the act became subject to frequent additions and deletions. We recognize that many of these revisions represented a sincere effort on everyone's part, including ours, to arrive at compromise language acceptable to all parties.

Unfortunately, I am afraid that despite these good faith efforts a solution upon which all parties can agree continues to elude us. Perhaps that is partly due to time restrictions imposed on key members of the subcommittee by competing hearings on the important farm bill and weeks long conference committee meetings. However, we think that for some time the members of this subcommittee have recognized and acknowledged that there must be a better accommodation than currently exists of the need for protection of proprietary research data, including health and safety information, and the public's right to be informed. We also perceive that there may have been too little attention devoted to the prospect of EPA's resolving the problem administratively within the framework of the existing law.

For these reasons we recommend that the problem of data protection and public access be remanded to EPA for study and evaluation. We ask that this subcommittee give a mandate to EPA to find a reasonable administrative solution or recommend a legislative one—a solution that will accommodate both the need to protect the confidentiality of industry data from competitors and the public's interest in being informed as to risks and benefits of registered products.

During this period of evaluation, the agency will have more time and resources than are available to the subcommittee in which to consider different types of solutions and resolve the problem.

We would also suggest, Mr. Chairman, that during this study period for some period of time that there is a mechanism that already exists within the Federal agency of EPA to allow public interest groups to raise questions of peer review and concern. We would suggest that the Scientific Advisory Panel, which is a prestigious scientific panel appointed from nominees of the National Cancer Institute and the National Academy of Sciences, could be utilized in the meantime as a mechanism to address public concern questions about the safety of our products.

In summary, given the difficulty of finding a solution to this complex problem in the limited time available this year for the legislative process and given the recognition that a better resolution must be found, we believe that the Congress should direct EPA to study the matter and attempt to find an administrative solution.

Insofar as the remainder of the draft of H.R. 5203 is concerned, we support the legislation with the following recommended changes. We do not believe that administrative consideration of the section 10 issues should adversely affect the passage of the amendments to sections 2, 3, and 24 that we support.

Specifically in section 2, Mr. Chairman, we support the new use definition provided it is expanded to include crop groupings that is currently under consideration by some of you.

In section 3 we would very much like to eliminate and significantly reduce the duration period of 18-month extension that EPA says is required to implement the cite-all concept. We believe that is a resolvable issue, but we do not believe it requires 18 months to bring it up to speed on this issue.

Also, Mr. Chairman, we are very much concerned about what is referred to as the disputes resolution mechanism within section 3. Frankly, it gives us no recourse to the process either through the Agency or in the court.

Also we need to look at certain technical changes because there are a few loopholes that need to be clarified, and they are minor but they may be important to others.

Also in section 24(a) we support the position that CSMA has presented to you today, and we urge you to adopt the language of the draft bill as written.

Finally, Mr. Chairman, there was a provision to what I refer to as the lawyers' relief act with the right to sue provision of section 16(e). We think it is most inappropriate and unnecessary because there is due course available to disenfranchise people in the State courts.

That concludes our prepared statement today. Dr. Wolf and I will be delighted to respond to any questions you and the subcommittee may have.

Mr. BROWN. Thank you very much. Dr. Wolf, do you have any comments you would like to make?

Dr. WOLF. I think Dr. Early did that very well, Mr. Chairman. That will suffice.

Mr. BROWN. Mr. Wampler.

Mr. WAMPLER. Dr. Early, I want to thank you for your statement this morning and for your long efforts to try to resolve some of these very difficult questions.

You have recommended, among other things, that we give a mandate to EPA to try to find a reasonable administrative solution or perhaps recommend a legislative one to this problem of trying to protect the confidentiality of industry data from competitors. I certainly share that concern.

As you know, Dr. Todhunter is scheduled to be our first witness this afternoon, and that's one question I'm sure we will direct to him. In the final summary of your statement you indicated in section 3 of the bill that one of the four concerns or recommendations that you would make would be to delete the disputes resolution mechanism. As I understand your organization's principal problem with this disputes resolution mechanism in section 3 of the bill, it would be your loss of the right to promptly rectify any possible Agency misuse of data under the so-called section 3 provisions by way of either administrative or judicial review.

My question is this. If this disputes resolution mechanism could be modified perhaps to provide a procedure for immediately suspending registrations that are improperly granted on the misuse of another company's data, then would that tend to satisfy your organization's objections?

Dr. EARLY. Mr. Wampler, that would go a long way, I think, toward satisfying our concern. I think you must recognize that the dispute resolution really leaves us no recourse either through the

Administrator or the courts. One of our member companies believes that his data submitted to EPA has been misused and misappropriated in some other form and so we think we are entitled to some recourse whatever it may be.

I will look forward to and would discuss this issue with EPA and I would hope we could resolve it.

Mr. WAMPLER. Mr. Chairman, I think many of the questions and recommendations that Dr. Early has presented to us this morning more properly should be directed to Dr. Todhunter so we can get the Agency response at that time.

I thank you.

Mr. BROWN. Mr. Fithian.

Mr. FITHIAN. Dr. Early, I want to thank you for your statement. I have an observation. The reference to the kinds of material that become available is one point you made. I'm talking about proprietary scientific methodology and product development information. Is that not pretty much covered under the trade secrets section so that that is not a relevant thing we're dealing with?

Dr. EARLY. Not at this time, it is not. Innovative methodology and the number of factors revolving around that are not presently considered trade secrets under the existing statute. That's a very sensitive issue. I'm sure you appreciate that.

Mr. FITHIAN. Are not we really talking about the public's right to know about the health and safety data? Isn't that really what the reading room concept is about?

Dr. EARLY. I think our concern is that any time that you take any expensive proprietary information and the Agency allows that out of their hands and not under their control, there is a much higher degree that the information will get into hands of those who would misappropriate and misuse the information.

Mr. FITHIAN. I understand the fears, but is there any example where that has happened?

Dr. EARLY. I think you understand why there are no examples because almost without exception those members of mine who are in the innovation or the business have gone through the court process to protect that innovation over the last 2 or 3 years.

Mr. FITHIAN. Is that court process exhausted now or do you have more time and more cases?

Dr. EARLY. Not being a lawyer, one would assume that the court options are never exhausted all the way, but I think the courts are beginning to speak to these issues based upon what is there in the statute now. I think that is what really concerns us. That's the only thing the courts were able to address—what was in the statute.

Mr. FITHIAN. My general impression was that the industry was ready to move on this pretty much because the normal court processes that you had been using to protect the data from being disseminated was pretty much running down and running out.

Dr. EARLY. I would not argue with that.

Mr. FITHIAN. That's what attracted you to the reading room concept in the first place I thought or some other vehicle by which we could do that.

Dr. EARLY. We looked at all kinds of options to prevent the innovative, very confidential information from getting into the wrong

hands. Certainly this is what we thought was a reasonable approach.

Mr. FITHIAN. Yes, and this is a quick observation—you said “Unquestionably I’m afraid that despite these efforts any solution to which all parties can agree continues to elude us.”

Is it not unlikely that, short of Eden, we’re not going to find a solution that all parties are going to sign off on? Maybe, Mr. Chairman, this might be premature for the committee to address this issue and I will not say how I’m going to go on any motion to strike the section 10 or to deal with the whole problem of reading rooms and the like, but it has been my experience over the last 6 years on this contentious piece of legislation where enormous amounts of money are involved that enormous amounts of interest are displayed by farm organizations and public interest groups and environmentalists and so on and that given the very nature of the beast I do not foresee a day in my lifetime when all parties are going to agree.

It seems to me it’s at that point that those of us who are paid to make difficult decisions ought to make a difficult decision. I do not know exactly what the decision is but it seems to me that putting this back on the burner one more round will not affect me directly. You all can fight this next year. It won’t affect me but—

Dr. EARLY. We will miss you, Mr. Fithian. I mean that sincerely. [Laughter.]

Mr. FITHIAN. As an observation, maybe this will never end. Maybe the FIFRA nightmare will go on forever. [Laughter.] However, I’m having a little difficulty. Without being too blunt about it, Mr. Early, it seems like your recommendation is a copout. That’s being too blunt, maybe.

Dr. EARLY. I don’t think you are being too blunt. I was accused of copping out before I came here.

Mr. FITHIAN. We recommend that the problem of data protection which is the problem, Mr. Chairman, that we’ve been fighting with since 1975 when I first stepped in to this committee and public access which is the alternative side of the coin which we have been fighting about since 1975 at least and probably before that, be remanded to the EPA for study and evaluation.

Isn’t this really the situation? Let me ask Dr. Todhunter that this afternoon. But isn’t this the situation that EPA has been running scared and trying to deal with data revelation with the renewed round of one court suit after the other? The people down there have been pretty much hamstrung.

Unless Dr. Todhunter is an absolute genius I do not think he’s going to pull a rabbit out of the hat on this either.

I don’t know how we get there from here. Maybe we were not as close as some of us thought we were on section 10. I didn’t think much of section 10. I didn’t think much of the reading room arrangement. I didn’t think much of the cards for admission and all that. It seemed like a terribly clumsy arrangement.

Dr. EARLY. I agree.

Mr. FITHIAN. But it was the compromise that was built in piece by piece by piece.

Now as I understand NACA is recommending that we scuttle all that. I’m not saying it’s a bad idea to scuttle it, but two or three

other witnesses this morning said they would favor the bill more if it were done in rather than amended. Maybe that's what we ought to do.

I'm trying to figure out why the conversion on the part of your organization. Let me speculate, I don't know what we're going to see coming back from the Senate, Mr. Chairman. Maybe there's something cooking over there that I do not know about. Maybe there's some solution that is far more acceptable to industry than the arrangement we have here or maybe a couple of friends at EPA who are going to administer this more vigorously to protect what is obviously a \$25 million investment across the board, and I understand that.

I suspect that if that is the case—if either of those are the case—that our chopping it out now will only thrust us into position where we will be under extraordinary pressures, and rightly so, either from groups that feel that they were left out all together when we dropped it or from language that is coming from the Senate which we have not been able to discover yet.

Or maybe there would be actions by the EPA which even the majority of moderate folks on this committee would not accept.

I do not know what's coming on this. I just know it's been a long, intractable problem and a legal one where the EPA has been tied up and much of its resources tied up by lawsuit after lawsuit after lawsuit. We all came in here a year or so ago and concluded that we have to do something about this. We have worked on it and we did not come up with a very good answer, and maybe that's a good enough reason for scuttling it. But I'm really wondering out loud how you solve this then by having this Congressman getting EPA to do something about it, but EPA has been incapable of doing anything about it for 5 years or at least since the 1978 amendments.

I'm troubled by this. I'm troubled because I don't have anything better than what Dr. Early has to recommend. Let me alert the subcommittee that it's my view, after wrestling with this longer than I really intended to, that this is not the solution, but maybe no solution is available to us.

Mr. WOLF. If we had a solution, we would be recommending it today, but we simply have come to the end of the stream of trying to balance what we consider to be very important issues on innovation versus the public's right to know.

It is a tough issue which we really do not know how to get from A to B at this point.

Dr. EARLY. May I offer a comment to Mr. Fithian's comments?

Mr. BROWN. Certainly.

Dr. EARLY. I appreciate your admittedly speculative comments you were making there, Mr. Fithian. Let me make this statement.

I think one of the issues we are facing here and which really gets to the guts of the issue is this. The EPA is set up and designed to protect the public—the private citizens, you and I—from being adversely affected in this process of FIFRA.

Over the years, I'm afraid that the EPA has not enjoyed the confidence of enough people either in the scientific community and certainly among the public. I would hope that whatever administration is running the EPA now or in the future that it will work

very hard to establish greater credibility. I think they already have some of that, and that's the crux of the matter.

If it works properly the way it should, then we should not have the so-called public interest groups second guessing a public interest group which is already within the Government.

I feel very strongly. Maybe it's one of those impossible situations to satisfy, but may I come back to this?

You talked about not being sure about copping out or changing the positions that you mentioned about me. This was a carefully thought-out process and it was not just my thinking. I took advantage of all of the industry's input. I think I did take that into consideration.

You know what we started out with with the reading room, and we stayed in the negotiation process for many, many months. We have compromised issues all down the line and we have seen our positions gradually cut away, cut away, cut away. Somewhere in late November and December I got the strong feeling I was no longer compromising but I was capitulating to a position that no longer satisfied my members' interest out there. We have moved too far over, and that was when we raised the question, "Are we going to be better off with H.R. 5203 right than what's in the existing statute?" Obviously neither one of them are acceptable, but I would be willing and I'd like to go the extra mile—and I'm not looking for miracles—but we would go the extra mile to give the regulating agency which has to deal with this under the new administration a chance to look at and see if they can't look at and come back with some magic solution to the problem.

As Dr. Wolf says, if we had managed a solution we would certainly put it right on the table this morning.

Mr. FITHIAN. One final comment. I will probably support the deletion of section 10. But let me say something that perhaps ought not to be a part of the record but maybe we can make a part of the record. I've worked off and on with EPA since I came here, first as a very bitter critic of that Agency, and later on trying to work on this law. It is now my overwhelming conviction and impression that things have never been as bad at EPA as they are right now, and that morale has never been so low nor so totally destroyed as it is right now, and that good scientists are bailing out of EPA at a very rapid rate, and that they're looking for jobs wherever. And that the Agency, if ever we remanded something to the Agency to do, that this is probably the worst of time.

I did a little checking. I did more than a little checking. I have a keen interest in this after all these years. I talked to some people and not the policymakers at EPA because they are hired and paid to give the administration line, but I'm talking about the working folks down there.

They are totally disillusioned from top to bottom and side to side. We even one time talked to a gentleman down there who didn't know I was a Congressman—I didn't tell him I was a Congressman, I didn't tell him I worked on FIFRA, I didn't tell him anything—and I happened to pick him up at a bus stop to make up a carpool from out where I live. I asked him where he worked, and he said he worked at the EPA. He didn't know anything about me. I started chatting with him about his job and his work, and he had been

with EPA since they laid the foundation block. He said something I want everyone to remember. He said, "I have never, ever in my life at EPA seen morale so low as it is right now."

That is what that agency is coming to. I do not know whether the Agency is either going to be able to protect your trade secrets and your interests or protect the public's right to know or anything else. I have great reservations. I'm not objecting scrapping section 10 at this point, but I want to tell the subcommittee that I do not believe for 30 seconds that the present EPA is up to the job that we have already mandated them to do. I do not even think they are close. I don't even think they are in the ball game. I thank you, Mr. Chairman.

Mr. BROWN. Mr. Fithian, I thank you. Mr. Panetta?

Mr. PANETTA. Briefly, Mr. Chairman. With regard to the question on trade secrets as I understand your argument, you are saying you really do not have any examples of that in fact happening because the information has not been provided since it has been bottled up in litigation. Right?

Dr. EARLY. That's correct.

Mr. PANETTA. Assuming that were not the case, do you have any substance to your fears about what would happen in the event that that information were disclosed? On what do you base your fear that in fact there are countries or industries that would do that if it were available?

Mr. WOLF. This is a very key issue. We do not have the cases that Mr. Johnson asked for because the data has been bottled up in the past. If you look at the whole agrichemical industry, the countries that have begun to import into here and take advantage of the fact that some patents have run out have large industries developing—Taiwan, Korea, Hungary, and in Israel. All of them are making compounds now that were discovered by mostly U.S. companies.

Let me share an example within our own company. We're about to introduce, after it is approved, a new herbicide on which we have spent \$40 million in research. If that data is available immediately to our competitors which we have submitted to EPA, there are a whole host of countries around the world that would register that product from any one source and who would never have done a dollar's worth of research and would have no safety of their own, but would simply be able to pick ours up and register it and sell the product.

Mr. PANETTA. I assume all the countries in the world have patent laws, but are there countries that do not have that protection?

Mr. WOLF. There are. There are some countries that have only 4 years of patents and there are some that have practically none. In some, you cannot patent the compound itself.

Dr. EARLY. Two or three hearings ago, I think we shared an example where a package of information was obtained in the United States, and they used that information without qualifications and registered the product overseas. I forgot where that was. It might have been the United Kingdom or France. It was a classic example of how you could take the information with no questions asked and present it to the other government who assumed it was yours and

you got it registered. So we did have a specific example. I'm not sure when it was exactly, but it was two or three hearings ago.

Mr. PANETTA. I understand your decision to refer this to EPA. It is my sense that there is chaos presently regarding efforts to determine exactly what will happen in this area. Courts have to make decisions with regard to the Freedom of Information Act, and there is the prospect of additional litigation.

On the other hand, there is the prospect of trying to develop some process within the legislation, admittedly complex and having its own problems, but nevertheless a process of trying to begin to analyze and balance the equities here.

Are you saying that you prefer to exist in the present chaos as opposed to moving this particular solution at this time?

Dr. EARLY. Yes, we do but with a proviso. Before EPA or this committee or the Congress arbitrarily releases our information, we are urging, inappropriate as it may be as Mr. Fithian says, at least one more party who is going to administer the law to have a look at it and make recommendations. There are a lot of down sides for us asking for no change in section 10. It was a deliberately careful thought-out decision.

Mr. PANETTA. Yes, I understand.

The question I have is this. A lot of minds have been brought to bear in developing the solution, as inadequate as it may be, and I cannot imagine that there are any brighter ideas out there in EPA or anywhere else. While you might throw the ball to EPA, how do you do so without seeing any better answers that will be forthcoming. Do you know of any possibilities that would be better than what has been presented here?

Dr. EARLY. There are a number of options that we've explored with the chairman, and he is familiar with those options, about the possibility of perhaps expanding the trade secret definition to give us greater protection for innovative methodologies and so on and residue chemistries and some of those that Dr. Wolf and his company think are very critical.

We have explored the possibility of the situation in Japan. There is an outside peer review of academicians which sits down and reviews the information before registration is granted by the regulatory agency in Japan.

The situation is Japan of course. With their style of government, one does not question the academician government. We are not quite in that posture in our society, although some of us might like for it to be that way.

So, we are second guessed and there have been some other options. We are open to any reasonable solution that we feel would give us something. But as we analyze what's in section 10 of H.R. 5203 right now we're now sure we have very much of anything beyond the statute.

Dr. EARLY. We are groping.

Mr. PANETTA. Yes, I understand that. Other groups are groping, too. In the meantime, we are in a quagmire. What I see being presented in terms of the testimony is that nobody particularly likes what has been reached in the sections that have been proposed, but nobody has any better idea as to how to approach it. So the end result is that this subcommittee, after months of trying to develop

some compromise language, is left with the conclusion that we ought not to do anything and let everybody remain in the chaos that presently exists.

You talk about providing welfare for attorneys. Any way you look, that's going to be the end result. It's unfortunate because in terms of the public interest which is involved here on both sides—on the part of the industry and the American public—in terms of health and safety, we are walking away from it, it seems. I don't particularly like to do that.

That's what seems to be the picture on both sides of the issue this morning.

Mr. WOLF. Mr. Chairman, I'd like to comment.

Mr. BROWN. Go ahead.

Mr. WOLF. The issue is how do we get our safety data from the industry out to the public which really needs to know? I have no argument with that and none of us do with a need to know that.

As an industry, I think we've done a lot better job over the last 10 years in communicating that through publications and through the medical centers and through our own organization to be certain. I suppose we in du Pont overcommunicate with our plantworkers to make certain that every bit of toxicity data they know as soon as we know.

There seems to be in your hearing a feeling that we are not communicating enough and that if they had access to all of our data they would come to a different conclusion than we do.

I find that very, very difficult to believe because all we're trying to really protect is our trade secrets, if you will, that would allow our competitors to get at our data and do something with it commercially.

So, let me share the way I feel about the safety data that we have. We tend to overcommunicate to everyone in the public area who want to know and feel they need to know. I think the industry as a whole does an awfully good job of making certain that information is out where it is needed.

Mr. PANETTA. Thank you.

My response would be that nevertheless, because of the issues involved here, there clearly needs to be a system of rules involved with this area. Once you establish that at the Federal and State levels there is a requirement to apply those rules, then there has to be a system and a way to implement it.

Mr. WOLF. I have no argument.

Mr. PANETTA. It's not a question of whether we're going to get there. We're already there. The question now is to develop a system to do it in an effective way that does not overburden the industry and also meets our requirements to protect the public.

I am left with the sense that if we pass a reauthorization of the bill to a large extent we can take all the testimony, and all the concerns, and all of the criticisms and throw them out the window because we have not really accomplished very much.

Dr. EARLY. May I comment?

Mr. BROWN. Certainly.

Dr. EARLY. I'll address this area. This has been bothering me for a number of years. We have never made an attempt to define

public in the review process of very technical and very scientific data.

I think any thoughts that these very complicated teratogenic and mutagenic studies ought to be put in the hands of the everyday citizens is not warranted. We would not know what we were looking at. We wouldn't know what we're talking about.

So, I do not think the public ought to have a look at this because they can misinterpret and aren't qualified and so.

I think what we need to do is have a mechanism by which we have scientists with the public interest groups and the industry comfortable with looking and making a peer review by a legitimate group of scientists like the National Cancer Institute, National Academy of Sciences, and so on rather than just the public out there.

I wouldn't know what I was looking at. We should keep that point in mind.

Mr. PANETTA. Yes, thank you. Thank you, Mr. Chairman.

Mr. BROWN. Let me offer two or three concluding remarks. I don't want to belabor this. First of all in the spirit of bearing our souls, I've developed considerable guilt feelings about our failure to come up with a better solution because, I think it goes without saying, that it's some reflection upon the capability and leadership of the chairman when you are unable to resolve a problem even as sticky as this. We do not like to appear to be in that posture.

I do appreciate the fact that you still have in mind, as you indicated, alternative solutions which we've discussed in the past—the expansion of the trade secret definition and some sort of responsible peer review which might be acceptable to both sides. I want to press that vigorously. I hope that the industry will give their best thought to that possibility, also.

Then of course one of the factors that has driven me in this is that outside of this committee in other settings I've been concerned for a number of years about the capability for innovation of American industry and what we can do to improve this. I looked upon this as a possible contribution to that process. It disappoints me that we are not able to do more.

If Mr. Panetta will forgive this remark, this is not the only sticky problem on which the Congress has punted because it couldn't find an acceptable solution, including budgetary and economic areas which Mr. Panetta is acquainted with.

Dr. EARLY. Two more short things. First of all, you are correct. Our industry is in a position where it would be foolish for us to close any doors no matter how small they may be opened for a possibility of resolution. We're always at that point.

Also, I think the chairman is being too hard on himself. I think the chairman has worked rather diligently to try to solve a very, very difficult issue. We appreciate your efforts. I'm just sorry as you have been that we're not at that solution point right now.

Mr. BROWN. Thank you very much. Gentlemen, you've helped us a great deal this morning in one way or another. [Laughter.]

Our last witness this morning is Dr. John Wise, president of the Pesticides Producers Association, from the great heartland of this country, Kansas City, Mo.

I understand Mr. Miller is going to substitute for Dr. Wise, and so, Mr. Miller, you may proceed.

STATEMENT OF GEORGE MILLER, CHAIRMAN, LEGISLATIVE COMMITTEE, PESTICIDE PRODUCERS ASSOCIATION, ACCOMPANIED BY DENNIS BURCHETT, VICE PRESIDENT

Mr. MILLER. Mr. Chairman, I am George Miller, past president of the Pesticide Producers Association. Mr. Wise was called away from Washington last night because of a family health problem. On my left we have vice president of the Pesticide Producers Association, Dennis Burchett. We appreciate being able to testify before your subcommittee, Mr. Chairman. I hope we don't have to come too many more times.

First, we would like to thank you and your subcommittee and their aides for all of the effort put in thus far on FIFRA. This has not been an easy bill. It hasn't been an easy time for any of us.

Second, I would like to correct rumors that seem to be going around. The PPA is not against changes in sections 10 and 24. As we have previously testified, we support changes in sections 10 and 24 and have not altered our positions. These two areas are delicate parts of FIFRA, and in our previous testimony we said we didn't know how to handle them ourselves so that everybody who were concerned groups were happy about it. We still do not. From the testimony I've heard today, I don't think anyone else has any better explanations.

We do know that our membership needs the changes in section 3, as does the rest of the industry. We would like to see as complete a bill as possible be reported out of the subcommittee; however, we request the subcommittee give serious consideration to passing section 3 no matter what else may happen to the rest of the bill.

We are unhappy about the 18 months needed by the EPA to move ahead on section 3(h) and feel that there are areas that should be implemented immediately as was done by the Agency on November 19, 1973. It seems unrealistic for someone who has their own data to continue citing someone else's data and offering to pay compensation during the 18 months the Agency states they need. We would prefer than anyone producing or citing their own data not have to cite anyone else's data.

We also oppose the addition of section 3(h)(K) to the act. In a time where EPA must utilize their resources to the utmost, this section will cost many additional manhours of workload which we can ill afford.

The amendments to section 16 of the act providing for judicial review and recovery of all costs attributed to a court case should be stricken from the law. This right is presently guaranteed by law and the additional costs would only increase the costs to the American farmer and consumer.

We would like to call to the subcommittee's attention that in the amendments to section 24(a) there is no relief given to the companies engaged in the production and sale of agricultural chemicals used for food or feed crops. Relief is needed in this area.

Mr. Chairman, if you have any questions we will be pleased to answer them.

Mr. BROWN. Thank you. We assure you that we appreciate your testimony and we appreciate the patience you have shown. Mr. Fithian?

Mr. FITHIAN. I have no questions, Mr. Chairman, until we come back this afternoon. We have some very important witnesses starting with Dr. Todhunter, the Assistant Administrator of the EPA.

Mr. BROWN. The subcommittee will be in recess.

[Recess taken.]

AFTERNOON SESSION

Mr. BROWN. The subcommittee will come to order.

This afternoon we are continuing with the review of the bill, H.R. 5203 with regard to amendments to FIFRA. We are going to start with representatives of the Environmental Protection Agency.

Is Dr. Todhunter here? He will be our first witness.

You are accompanied by Mr. Gray.

STATEMENT OF JOHN A. TODHUNTER, ASSISTANT ADMINISTRATOR, PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY ED GRAY, OFFICE OF GENERAL COUNSEL

Mr. TODHUNTER. Thank you, Mr. Chairman.

I am accompanied by Mr. Gray.

Good afternoon, Mr. Chairman, and members of the subcommittee. I am John A. Todhunter, Assistant Administrator for Pesticides and Toxic Substances in the Environmental Protection Agency.

I welcome this opportunity to comment on H.R. 5203, a bill which would amend the Federal Insecticide, Fungicide, and Rodenticide Act, better known as FIFRA.

These views are essentially those expressed earlier in Dr. Hernandez' letter of November 17, 1981. Although I am pleased to provide you with these technical comments, I must emphasize that our experience thus far has not revealed any compelling reasons for changing the law at this time.

I also welcome this as my first opportunity to appear before this subcommittee. I am looking forward to a good working relationship and productive dialog with the committee over the next several years.

As you know, one of the basic tenets of this administration is to implement the laws as Congress writes them and to follow congressional intent carefully.

It is, therefore, especially important to have a good understanding between the authorizing committees and the Agency which carries out the will of those committees.

Inasmuch as the subcommittee has focused particularly on sections 3, 10, and 24(a) in these proposed amendments to FIFRA, I will concentrate on these sections in my remarks this afternoon.

As you will recall, the Agency provided in-depth comments on these three sections of FIFRA in Dr. Hernandez' November 17, 1981, letter to the chairman responding to an earlier committee print.

Inasmuch as the concepts of the proposed legislation have not changed in principle since that committee print, our original comments are still pertinent.

Allow me to discuss the changes to section 3 first. The language is much improved over earlier drafts. We are especially pleased that our suggestions have been adopted concerning resolution of disputes over what data are adequate to complete the minimum data set needed for registration.

We do have some drafting problems with a new part of section 3(c)(2)(B) which we have explained in a separate attachment.

I would ask that be placed in the record.

Mr. BROWN. Without objection, so ordered.

Mr. TODHUNTER. Briefly, the system allowing for cost sharing when a company voluntarily initiates defensive data needs to be described more precisely. Other minor changes suggested would make the provision easier to implement.

I would like to reiterate three points on section 3 that Dr. Hernandez made in his November 17 letter.

First, we want the Congress and the public to understand that we are talking about a fundamental tradeoff here—additional complications to section 3 will work against our efforts to speed up registration actions and reduce backlogs and paperwork.

It is a simple fact that the additional tracking and administrative demands on EPA under the new section 3 will be reflected in a diminished ability to address these other priority goals of the program.

Second, we are still unenthusiastic about the provision to extend exclusive use protection to data submitted to support a new use of an already registered pesticide.

This provision offers the greatest complicating factor in administering the amendments. The more exclusive use "clocks" there are, the more potential for paperwork, confusion, and misunderstanding.

In addition, this provision raises anticompetitive concerns which the committee may wish to consider. Third, I am concerned about the relationship between exclusive use and reregistration. As you know, the Agency is proceeding to develop registration standards on previously registered pesticides to bring the data base up to date.

The whole data base would then support the registration of previously registered pesticides. If the data in the base are sprinkled with exclusive use prohibitions, I can envision great complications in reregistering products.

In FIFRA terms, it seems to me that the benefits of such a system to industry incentive may be outweighed by the administrative complexity and burdens that the system will impose.

Concerning section 10, Dr. Hernandez' comments in his November 17 letter are still pertinent. The reading room for examining the information on which Agency decisions are based.

We can implement this provision. However, as Dr. Hernandez pointed out earlier, our administrative costs and paperwork will increase as would the user fee which is charged for making this information available to requestors.

We would run the system on a request basis, and data would not be released more quickly than it is under the present procedures.

Whether this system actually provides more protection for industry data than is currently available is questionable. As with section 3, we have some minor technical changes to suggest to make the provisions concerning predisclosure court review and "scrubbing" data easier to implement.

I would ask these be placed in the record.

Mr. BROWN. Without objection, so ordered.

[Technical changes follow:]

TECHNICAL CHANGES SUGGESTED TO 3(c)(2)(B)
AS WRITTEN IN H.R. 5023

The Agency suggests a number of technical changes to proposed FIFRA section 3(c)(2)(B) in the December 14, 1981, version of H.R. 5023, the FIFRA Amendments of 1981. Below is a statement of the proposed changes and why they are necessary.

I. Changes in proposed section 3(c)(2)(B)(v) to clarify ambiguities and ensure that the drafters' intent is achieved.

As amended it would read as follows:

"(v) Health and safety data may be submitted voluntarily by a registrant or applicant after September 30, 1978, to replace data which he deems scientifically insufficient under generally accepted good laboratory practices or test standards. In order to obtain the rights provided by this clause, a registrant or applicant undertaking such a replacement study shall notify the Administrator that the replacement study is being performed or has been performed under this subparagraph. The Administrator shall publish any such notification in the Federal Register promptly after its receipt. Each person who, as of the date of such publication, is a registrant or an applicant for registration of any product containing the active ingredient which is the subject of the study shall have the opportunity to participate in a joint data development arrangement as provided in clause (ii) of this subparagraph. If a registrant or applicant of record as of the date of publication of the notice informs the person undertaking the study, within 90 days of the date of publication of his decision to voluntarily participate, the provisions of clauses (ii), (iii), and (iv) of this subparagraph shall apply. Subsequent applicants and registrants and those who do not voluntarily participate as above shall be entitled to participate as provided in subparagraph (iv)."

The changes are intended to:

A. Eliminate a confusing reference to 3(c)(2)(B)(i) in order to make clear that under 3(c)(1)(d)(v) the registrant, not the Administrator, initiates the process of notifying other registrants that he is voluntarily undertaking testing to replace data he deems scientifically insufficient. (Under 3(c)(2)(B)(i), it is the Administrator who is to determine when testing is needed, to notify registrants of this determination, and to require that testing be done.)

B. Specify a method for informing other interested parties (i.e., applicants as well as registrants) that tests subject to FIFRA sec. 3(c)(2)(B)(v) are being performed, identify the persons who may opt to be "original data submitters" under clauses (ii), (iii), and (iv), and thus eliminate the possibility that prejudice or error in notification on the part of the undertaking registrant deprives any applicant or registrant of the right to participate.

C. Ensure fairness to the undertaking registrant by limiting to 90 days the time within which applicants and registrants may exercise their option and by specifying that all others participate as per 3(c)(2)(B)(iv).

II. Changes in 3(c)(2)(B)(iii) to eliminate the requirement that EPA enforce compliance with a joint data development arrangement. It is important to EPA that the persons to whom the requirement applies take appropriate steps to submit and secure the data and to form a joint data development arrangement. However, once the agreement is formed in accordance with law, the parties to it have rights vis-a-vis each other that can be judicially enforced without Agency oversight, participation, or expenditure of resources.

Accordingly, proposed section 3(c)(2)(B)(iii) should be amended by: (1) inserting the word "unlawfully" before the word "fails" in line 8 on page 7 of the bill; (2) deleting the words "participate in" in line 9 on page 7, and substituting therefor the words "enter into"; and (3) deleting the words "or at any time fails to comply with the terms of such an arrangement," in lines 10 and 11 on page 7.

III. A change to facilitate EPA's dealings with a group of joint data developers. We suggest that section 3(c)(2)(B)(ii) be amended by inserting the following sentence after the words "of this paragraph" in line 23 on page 5:

"The joint data developers shall furnish to the Administrator the name, address, and telephone number of the person to whom inquiries concerning the arrangement should be addressed."

TECHNICAL CHANGES TO §10
AS WRITTEN IN H.R. 5203

The Agency believes that the bill's amendments to FIFRA, section 10(c) -- designed to specify the circumstances when pre-disclosure court review is available -- could be stated more clearly. Also, we think it would be useful to specify when review under section 10(d)(4) [current 10(d)(3)] is appropriate in lieu of review under section 10(c). Accordingly, we suggest that:

(1) The language starting on line 17 of page 32 of the bill, and ending on line 5 of page 33, be deleted, and that the following be substituted therefor:

"(c) DISPUTES. --

If the Administrator proposed to make the initial public disclosure of any item of data which the data submitter believes to be protected from disclosure by this section, but which the Administrator has found is not so protected, the Administrator shall notify the data submitter, in writing, by certified mail. The Administrator shall not thereafter make the item of data available to the public until 30 days after receipt of the notice by the data submitter. During this period, the data submitter may institute an action in an appropriate district court for a declaratory judgment as to whether such information is protection from the proposed disclosure. This subsection shall not apply to any proposed disclosure under subsection (d)(4) [old (d)(3)] of this section."

(2) Amend the first sentence of new section 10(d)(4) [old section 10(d)(3)] by deleting the words "described in" and substituting therefor the words "he has determined is described by."

We also propose some style and conforming changes to the portion of the bill's proposed amendment to FIFRA section 10(d)(2) dealing with "scrubbing" data to ascertain which items are nondisclosable. On page 34 of the bill:

(1) in lines 14 and 15, delete the words "applicant has previously determined as not containing" and substitute therefor the words "data submitter has previously stated do not contain."

(2) In lines 16 and 17, delete the words "data submitter that originally submitted" and substitute therefor the words "original submitter of."

Mr. TODHUNTER. Concerning section 24(a), we understand the problem industry would confront if each State imposed additional data submission requirements.

We are sympathetic to industry's position that a product which has met stringent Federal registration requirements should not have to undergo a myriad of additional clearances.

However, we are troubled by the proposed amendment as it bears on the prerogatives of the States. Further, we oppose the role of arbitrator between industry and the States thrust on the Agency by the bill, and this leads us to oppose the section 24(a) amendment.

There are several other provisions of the amendments I would comment on briefly. There are worker protection amendments which provide that:

One, EPA shall develop guidelines for worker protection within 1 year of passage;

Two, that retaliation against individuals for reporting FIFRA violations is prohibited; and,

Three, that anyone aggrieved by misuse of a pesticide can bring suit in U.S. District Courts.

We are in support of the hortatory language of the bill which urges EPA to consider risks to farmworkers and other individuals who encounter pesticides in their work as part of our responsibilities in carrying out FIFRA.

We would respectfully request the committee, however, to reconsider specifying the manner in which we are to devise and implement worker protection procedures, since guidelines may or may not be the most effective means to accomplish the stated goal of the amendment.

Worker and applicator protection are more fundamentally addressed in the registration, reregistration, or cancellation processes.

In addition, I do not believe it would be possible to accomplish all the goals stated in the amendment in just a year. We are unsure that FIFRA is the right place for the antiretaliation and court access amendments, since they may confuse current authorities and remedies.

Concerning the amendments on the cooperative training and certification programs and the State enforcement provisions, we have no objections to the funding authorization.

We are sure that the subcommittee realizes that it will be the budget process that determines the amount of funds within the authorized ceiling that will be devoted to training and certification.

The changes to sections 26 and 27 are consistent with our current policies.

The amendment to section 3, as does current section 3, requires EPA to publish guidelines in the Federal Register. Let me make clear our policy on publishing guidelines.

Before I came to EPA, the Agency was proceeding to publish all data requirements and protocols in the Federal Register as rule-making. I have made the decision that only a small segment of those guidelines—the portion that specifies when data are actually required—need be published as rules in the Federal Register.

The bulk of the protocols will be made available to the public and the industry through the National Technical Information Service.

This new approach will permit more scientific flexibility and enable the Agency to more easily reflect changes in the state of the art.

I believe this approach is consistent with the bill's language on guidelines, but I wanted to make sure there was no misunderstanding on what would and would not be published in the Federal Register.

Before closing, I would like to express my concern about the reauthorization of the Scientific Advisory Panel, or SAP.

As you know, the administration urged the Panel's reauthorization before the end of last fiscal year and the committee reacted favorably by reporting a bill providing for the extension of the SAP as well as authorizing appropriations for fiscal year 1982.

We are in the process of selecting new members of the Panel now. However, we cannot proceed much farther until we have the statutory authorization restored that expired on September 30, 1981.

I would respectfully urge the subcommittee, then, to obtain enactment of the already reported bill regardless of the action the committee takes on H.R. 5203.

That concludes my formal remarks, Mr. Chairman. I would be pleased to answer any questions the subcommittee may have on our views on H.R. 5203.

Thank you.

Mr. BROWN. Thank you very much.

I think you have given us a very clear picture of the Agency's stand on this issue.

Mr. Fithian?

Mr. FITHIAN. Thank you, Mr. Chairman.

Dr. Todhunter, we want to welcome you. We wish you well in your endeavors to administer the act.

I have several questions. I would like to ask a couple and then after other members get through, I can have a second round of questioning.

You say on page 3 of your prepared testimony that: " * * * we are still unenthusiastic about the provision to extend exclusive use protection to data submitted to support a new use of an already registered pesticide.

"The provision offers the greatest complicating factor in administering the amendments."

Let me pose a problem that I perceive out there. Let me see if we cannot get some understanding as to where you are coming from.

I recognize, of course, that if you add to your burden to registration of new use pesticides to that data which you have already compiled on the basic compound, and which you have handled, then you have a problem.

But as I understand the economics of the whole field, a major company gets involved and invests anywhere from \$5 to \$40 million, which we were told about this morning.

That basic development would only be possible for a major use pesticide, like something for corn or wheat or cotton or whatever.

We do have a lot of speciality crops and a lot of small uses or lesser uses for some of these and adaptations. But as I understand the general industry's thrust, they go for the big ones first to try to recover their investment of R. & D. costs.

That is totally understandable. But the question is this. I wonder whether or not we can, under the present system, stimulate them to run another series of tests to see whether the residue on apples, or whatever it is, is such that we could use that pesticide for a different use.

Maybe they will have to run certain laboratory tests to do that.

Clearly, the return would never cover the basic R. & D. done on the compound, even if they had exclusive use forever on that smaller use. They would never recover.

We in the agricultural field want to see these adaptations, but we also have a responsibility to see that they are not harmful to the public.

Weighing those off, it seems to me that we would be advised and would be well advised as a committee, to try to figure out some way to give them the additional incentive to do an additional set of tests, probably much less complicated and less expensive than the originals in order to find out whether or not it was adaptable and useable for a new use.

But unless you give them some economic incentive, then how do we, in fact, get that done?

The thought of giving them a new clock to run for 15 years, or whatever it is, for a new use came quite obviously as the obvious solution.

The idea behind that is that the only additional use that an industry would get, that is, the exclusive use protection, would not be for the data that is submitted 7, 8, or 10 years ago, but just for the data that is new.

Maybe that is not a good tradeoff. I do not know, but we are trying to grapple with a significant problem, particularly for the minor uses and for the adaptation of a presently used and registered pesticide to some other use.

I can tell you I do not think they are going to be in this philanthropically, so if that is done, it is going to be because they have a handle on something they can make some money out of. That is the way the system works.

So, I raise that as a philosophical and economic question. I am sympathetic to the additional burden of administration, but short of doing something with new use, I fail to see how we are going to encourage the industry to move over into the additional use patterns.

I would appreciate your comments on that.

Mr. TODHUNTER. As I understand your question—and I will try to rephrase the gist of it, and if I have misunderstood please correct me—your concern is for some stimulation of development and application for registration on minor uses and minor crops.

Is that basically your questions?

Mr. FITHIAN. Yes. In other words, if we do not allow them some protection, then how do we build in an incentive to cause them to go into the additional use testing?

Mr. TODHUNTER. The economics are very important in this. Right now we do have a situation in which it is difficult sometimes to get the major manufacturers to come in in terms of the minor uses.

We do have a minor use policy. It is not clear that extending this protection to new use would provide a large economic stimulus, given the fact that for many of the crops the market would be quite small anyway.

The protection that the bill would provide basically would be one in which if a second company wanted to come in they could duplicate the tests so that the protection conceivably could be only for 1 or 2 years anyway.

Once some company identified a minor crop that now might have a promising potential to market into, then that would be the case.

Right now the Agency has tried to work with the various university extension services to try to promote some relief for farmers for the IR-4 projects.

This group has been active in submitting to us petitions for tolerances on minor crops and things like that.

It is not clear to us that for the incremental protection to the industry that the administrative burden might be worth it. I would ask the committee to consider that.

Mr. FITHIAN. I have a second question.

Do you visualize the Federal EPA as a body which would bring about some national minimum standards and some uniformity to the way we handle pesticides across the country? Is that a part of your view of the EPA?

Mr. TODHUNTER. That is something with which we are currently proceeding with respect to data requirements for registration. We have been developing guidelines for data requirements. These shortly will be out as a proposed rulemaking for comment.

This would provide a national standard.

Mr. FITHIAN. I gather you and I look upon the EPA's function as essentially the same. I am puzzled by your statement on the bottom of page 4 where you say: "* * * we oppose the role of arbitrator between industry and the States * * *" as would be brought about by the new proposals for section 24 and the amendment to section 24(a).

As I see it, this committee cannot be the arbitrator. The Congress of the United States cannot be the arbitrator. We have seen enough arbitration in the courts to know that your operation has been seriously hamstrung.

I do not see any other arbitrator around except you fellows. I think that is what lies behind our thrust of section 24.

I am not saying it is a comfortable role to be in the role of an arbitrator. I am saying that is what I kind of see as your role, as I do not see anybody else out there that we can substitute for that role.

I would like for you to expound a moment on how you see our handling the conflict between the State and the industry, or the producers and the farmers, or whatever it is, if, in fact, we have a Federal role to play here, if we do not do it through a Federal agency.

We do not have any jurisdiction over the Kansas Department of Agriculture, per se, or their EPA equivalent. The only tool we have

for dealing with this national situation in terms of a norm would be the Federal agency.

Maybe there is some other way of doing it other than this section, but I do not know.

Mr. TODHUNTER. Your desire for an arbitrator or some mechanism to resolve the disputes is, of course, understandable. I wish to emphasize that our opposition to section 24(a) stems philosophically from our commitment that the States need to have more control over their personal affairs, their local matters.

Right now the situation exists and possibly it is one way in which it could be resolved, in which the State courts could view the reasonableness of State requirements.

Mr. FITHIAN. Bear with me one more moment, Mr. Chairman.

The only agency in the United States that has collected the scientific data on all of this is the EPA. How can we expect this of any other group, like the USDA or somebody else?

You are the possessor of that information down there. All the data is on file with you.

I have a great deal of difficulty understanding your thought that the Federal Government, through the EPA, ought not get involved in this role.

Mr. TODHUNTER. I have not said that we do not want to get involved totally. We have no objection to serving as an advisory capacity to the States to share with them, to the extent feasible, information in allowing the State to identify which data gaps do, in fact, exist.

But we have this aversion to being placed in the middle in arbitrating a dispute between the State and industry.

Mr. FITHIAN. Yes, I understand, but as the chairman said this morning, the broad problem was laid out. There is the question of interstate commerce, which is raised by the situation we have.

If that is the case, then the Federal Government, by 200 years of constitutional precedence, is the functioning body, and within the Federal Government, it is the EPA for insecticides.

I just keep coming back around to this. I find the argument that it should not be the EPA doing it. This is very curious. There is no one else to do it.

Mr. TODHUNTER. With respect to interstate commerce in pesticides, we only have the jurisdiction which Congress gave us.

Mr. FITHIAN. Some here are proposing to give you a little more jurisdiction.

I will come back later for other questions, Mr. Chairman.

Mr. BROWN. Mr. Wampler?

Mr. WAMPLER. Thank you, Mr. Chairman.

Dr. Todhunter, I want to thank you for your statement and for bringing our friend, Mr. Gray with you. We have spent many hours here together in this committee. We appreciate the cooperation that he has always extended to the committee representing your Agency.

On the last page of your prepared statement you express concern about the reauthorization of the Scientific Advisory Panel.

I want you to know I share that concern, and I have been among those on the committee who felt like the Scientific Advisory Panel to your Agency has served a very useful purpose.

You may recall that I did request of your Agency some time ago some suggested statutory changes as to how we might make the Scientific Advisory Panel more effective. You have indeed shared that with us, even though I must say that I do not want to be presumptuous because I understand this language has not yet been approved by the Office of Management and Budget.

I recognize that caveat. I think what you have proposed indeed is good because among other things you are suggesting that you draw from nominees from two additional scientific groups, the Society of Toxicology and the American College of Toxicology.

I think this does increase the chances of our receiving nominations for scientists who would be holding, perhaps, appropriate human health and environmental hazard assessment credentials.

Certainly it would be our purpose to pass the authorization that you need. I do want to thank you for supplying that. We will consider that at the appropriate time as becoming an amendment to FIFRA.

If I may for just a moment, I would like to direct a question concerning section 3 of the bill that is before us today.

We had one witness this morning, and perhaps others, raising concerns about section 3.

As you know, under the current bill, EPA would take up to 18 months in which to have the cite-all concept and to implement the new provisions of section 3 that will allow applicants to rely upon the minimum amount of data required to support a registration.

I think I could appreciate that the Agency would need to have a transition period from the current cite-all concept to the new registration provisions of section 3.

I wonder why it should not be possible for the Agency to give applicants the right to rely solely on the data that they generated in support of their own applications without having to continue the use of the cite-all method.

Also, it seems to me that the 18-month transition period may be an excessive time in which to implement the new section 3 provisions, and perhaps a lesser amount of time, or maybe one-half that period, might be a more appropriate transition time.

Is there any reason why the Agency could not immediately implement the right of an applicant to rely entirely upon his own data to support this registration?

Is there any reason why the Agency then could not reduce the 18-month transition time for the rest of section 3 amendments down to what perhaps could be considered a more reasonable time?

Mr. TODHUNTER. I would be pleased to respond to that in part.

With respect to the basic problem of putting into play a newly enacted law with the amendments, there is going to be some amount of training and transition period for our staff who are used to doing things one way and have their data system set up to accommodate it as it exists and to transfer those functions over.

It is possible that there may be differences between the situation where an applicant comes in with completely their own data.

I would be happy to respond to that specific part of the question in writing once we have a look at it and see how much different it might be from the other situation.

However, with respect to having some substantial leadtime, like the 18 months we talked about, after all, it is going to be very difficult for us to implement anything having to do with cite-all changes or compensability of data until we have gone through and looked at the data we have and have characterized it.

After all, the bill does provide 12 months for us to have an index prepared of data covered under these amendments.

Mr. WAMPLER. You will supply additional answers in writing?

Mr. TODHUNTER. Yes.

Mr. WAMPLER. Thank you.

Mr. BROWN. Without objection, that material will be placed in the record at this point.

[The information supplied appears at the conclusion of the oral presentation of Mr. Todhunter.]

Mr. WAMPLER. I am sure you are aware of the controversy that surrounds section 10. In the hearing this morning and in view of the various concerns that have been expressed to the subcommittee regarding the need to find a better way of protecting research data from the consequences of disclosure to competitive interests under section 10, and also the legitimate need for assuring the public's right to be informed concerning the risks and benefits of pesticides, it has been suggested by some of the witnesses and other interested parties that this committee might consider the possibility of referring these questions to the Agency to see if it is possible to find out if there is an administrative solution that can be worked out under the framework of the existing law.

What I would like to ask you today is if these questions are referred to EPA for study and evaluation for the purpose of trying to find this administrative solution, is it your feeling that you might find some reasonable method for doing this?

Or, if you could not, do you feel like you might be in the position of recommending to us appropriate legislative amendments if you thought they were necessary?

Mr. TODHUNTER. Well, I am going to have to refer to a comment made earlier this morning. I do not claim exclusive genius. The Agency cannot claim exclusive expertise in this area.

It is generally our belief that there probably is not an administrative solution to this dilemma. It probably requires some legislative solution.

That being the case, we feel that we would be more than happy to work with the committee to try to work that kind of a situation out, but we feel that legislative decisions on matters of such fundamental policy is the way to go.

We think it is really the right and prerogative and it is appropriately placed within the Congress.

Mr. WAMPLER. Let me pursue that just a bit further.

Assuming it were referred to you for your study and evaluation, while you have it under study, let us assume that questions arose concerning the risk posed by a particular product as a result of certain scientific studies and tests.

Would it not be possible for the Agency to refer such questions and the scientific data to your own Scientific Advisory Panel as a way of satisfying perhaps a need for public information and even perhaps peer review for considering these kinds of risks?

Mr. TODHUNTER. The Agency very recently published a set of peer review procedures for actions under FIFRA which were published in response to an amendment sponsored by yourself which involved the Scientific Advisory Panel in reviewing major studies supporting pesticide actions.

The problem that arises, however, is that while we normally would let the Scientific Advisory Panel review something prior to registration and while individual members could look at something on an individual basis, but once a product was registered and went to the Scientific Advisory Panel in terms of having a study go to them, that Panel operates under the strictures of the Federal Advisory Committee Act, and, as such, they cannot keep things secret.

They cannot keep things to themselves while they review that study and deliberate. So, I am not sure that would provide the solution.

Certainly it does provide—and I think this was recognized in your amendment which was enacted in 1980—that the Scientific Advisory Panel can serve as a representative of the public since it is an autonomous body and not governed by us in order to assure the public that there is a good quality of science being done.

It does serve as a quality control on EPA actions to assure that the Agency is acting on the basis of sound science.

Mr. WAMPLER. I would like to pursue one more question.

Let us assume for the moment that we are going to refer this matter to you for finding an administrative solution which is something that we have been unable to resolve ourselves.

I can only speak for myself, but if that happens I would certainly hope that the Agency would be sensitive and aware to the need for providing appropriate protection to the scientific data and would realize there is some need to prevent any irreparable consequences during that period of time that the study would be underway.

I assume that the Agency would be aware of that responsibility.

Mr. TODHUNTER. As I stated in my opening comments, we are most sensitive to the intent of Congress as they enact laws and as they give us charges. We certainly do try to be responsive to those things.

Mr. WAMPLER. From discussions that I have had with you and in your prepared statement, I think you are fully aware of what your dual responsibilities here are in terms of protecting data.

But, at the same time, the public interest and the right to know is there. I do not offer this as a criticism of the Agency, but I simply want to commend you.

As you well point out, the Scientific Advisory Panel has served as a check and balance simply to assure the public that we do have an objective group of scientists who are looking at what you are doing and you are referring questions to them in the concept of peer review that ought to enhance the degree of credibility that the Agency should have.

I commend you for your concept and understanding.

Mr. TODHUNTER. Thank you.

I would like at this point to put in something for the technical personnel in our Office of Pesticides and Toxic Substances.

I have found one of the pleasant surprises coming into the Government that we do have some good people down there. I think the public should have confidence in what they do.

Mr. WAMPLER. I share that view. As you well know, in the past I have been considered by some as being critical of the Agency, but I certainly agree with you that you do have competent people.

We want to fully utilize their talents so that they have the opportunity to do what I think Congress intended for them to do when they amended FIFRA.

Thank you, Mr. Chairman.

Mr. BROWN. Mr. Emerson?

Mr. EMERSON. Thank you, Mr. Chairman.

Dr. Todhunter, I would like to ask a question that is not directly related to the amendments of this committee, but it is relative to the administration of FIFRA by EPA.

I was visited earlier today by the supervisor of the treated timber program of the Missouri Department of Agriculture as well as several people in the wood-preserving industry.

I would like to relate their concerns to you. But before so doing, let me compliment you on your affirmation that you intend to implement the law in accordance with the intent of Congress.

Perhaps what I am going to relate to you is a starting point for EPA to assess its implementation practices vis-a-vis the intent of Congress.

It is my understanding that EPA is attempting to regulate the end use of treated wood products under FIFRA. For example, this includes fenceposts, corral fencing, utility poles, and other farm materials, such as barn siding.

Because treated wood is not included in the definition of pesticides under FIFRA, I am concerned about the regulation of this product under FIFRA by the EPA.

I will be sending a letter to you regarding this situation and I do not really expect you to respond to me today, but I wanted to make you aware of the problem. I will be in touch with you. Feel free to comment now, if you would like, but it is a serious problem and deserves your consideration.

Mr. TODHUNTER. We have been contacted by representatives of the end-use products, by representatives of the wood preservers. We are aware of their concerns.

Mr. EMERSON. Thank you.

Thank you, Mr. Chairman.

Mr. BROWN. Mr. Todhunter, going back to section 10 for a moment, could you give us a little prospective as to what the Agency has in mind with regard to the release of data at the present time in view of the apparent conclusion of the litigation with regard to this matter?

Mr. TODHUNTER. Yes; we have received Freedom of Information requests for certain items of data. These requests are being evaluated through our Freedom of Information Office and I believe also by the Office of General Counsel for advice as to which portions of data would be covered by these requests.

Naturally, we would have to check within our office as to the content of any trade secret information and studies before we could release them in the response to Freedom of Information requests.

Mr. BROWN. I had the impression that you had proceeded to previously examine these with regard to the trade secret aspects and perhaps I was under a misimpression that you had completed most of that.

Am I incorrect in that?

Mr. TODHUNTER. No, sir, you are not incorrect in that. But what I am rather trying to say is that in an area which is as sensitive as this, we try to have a level of quality control over the screening of information for trade secrets just as we do on the toxic side of our program where we make every attempt to very scrupulously keep that material which is, in fact, confidential business information confidential.

Mr. BROWN. Are you giving any consideration to possible revisions in the definition of trade secret material?

Mr. TODHUNTER. That is a matter upon which the Administrator has been requested to comment. I do not have a comment on that.

Mr. BROWN. The testimony this morning established what we had begun to sense that the present language of this bill with regard to release of data is not satisfactory to any of the parties.

Mr. Fithian has commented on that. We heard no witnesses who enthusiastically endorsed this. Most of them took the opposite point of view, suggesting instead such alternatives as passing the ball to you to see if you can come up with better suggestions.

You have kind of lateraled that one also, so we are really not sure where we stand.

Let me inquire as to one possibility which has been suggested and that is that you consider certain categories of data which could be released expeditiously.

For example, I think chronic toxicity studies have been mentioned in that regard. You develop expedited procedures for the release of that kind of data.

Is that sort of an approach something that might be reasonable and noncontroversial from your standpoint?

Mr. TODHUNTER. That has legal dimensions to it. It would depend on the interpretation of the statute. That is one if you would wish an answer, I would request we be allowed to respond in writing after the counsel's office has had a chance.

Mr. BROWN. Could you give us an answer to that within a period of a couple of weeks?

Mr. TODHUNTER. Yes; I believe so.

Mr. BROWN. I only suggest that in the interest of the subcommittee trying to make an expedited decision as to whether to adopt this section entirely or to consider some hortatory language as you described it in other sections.

Without objection, that will be placed in the record at this point. [The information supplied appears at the conclusion of the oral presentation of Mr. Todhunter.]

Mr. BROWN. Mr. Fithian, are you ready for further questions?

Mr. FITHIAN. Yes, Mr. Chairman.

Dr. Todhunter, in the present section 3, it is proposed to grant an 18-month extension to you to computerize the data and get it ready to go in order to get us out of the woods on this cite-all concept.

Would it not be possible for you to administer the law if we simply said that during the 18 month period instead of waiting the

whole 18 months that anyone could go ahead and register if they were providing their own data?

In other words, it would not put you in a bind if we said that as of a certain time now that if they were only citing their own data and if your people credited it as being adequate to meet the requirements, that they should be able to go ahead and register the pesticide.

Would that cause you any problems?

Mr. TODHUNTER. There would be some amount of transition time involved, as I stated earlier. It is quite possible that we might be able to do that more quickly. That is something that I believe I had committed to respond to in writing once we analyzed how much more quickly and how much more different that situation could be.

Mr. BROWN. Without objection, so ordered.

[The information supplied appears at the conclusion of the oral presentation of Mr. Todhunter.]

Mr. FITHIAN. I have a followup question. Let me ask a followup question to Congressman Brown's question and that is whether or not you could split the data in different ways than we have discussed here in the committee over the last several years so far as making available to the public the information.

If we had contests—and we usually have enough interest in this—would it be possible to work out something that Mr. Wampler was getting at and that is to extend or modify the role of the Scientific Advisory Panel so that they can handle these things and be the referee, so to speak?

Could we conceive of a system whereby we could expand the role of the Scientific Advisory Panel to be the peer group review body that some of us envisioned it originally?

At the same time maybe we could solve the critical need—and I think the right—of public interest groups to have the acute toxicity studies or the cancer studies side of this made available to them?

Is there a possible combination of the two that we could make workable to come out of this rather than punting?

Mr. TODHUNTER. The best answer that I can give to that immediately is that under our now proposed peer review procedures for those decisions which were controversial, as we defined them in our proposal, the Scientific Advisory Panel would review supporting studies.

That may, however, only in part address the problem because that which the Scientific Advisory Panel reviews is information which is then accessible to the general public.

If I understand correctly the industry's concern, it is that their studies may be pirated, if I may use that term, and the study used to support registration in some foreign country and that they would not know about it and have little control.

Certainly, the Scientific Advisory Panel does address the question of assuring the public that what has been done has been done well. It certainly does, but I am not sure it takes care of industry's concern about how to protect what they feel to be proprietary information.

Mr. FITHIAN. I have one additional comment.

We have been wrestling with some of these problems, at least since 1978. There is the cite-all problem and the problem of the

States and even some problems which we have not addressed right here today and that is the training provisions and the funding of the State's training programs and many other problems.

After all the wrestling we have done in which the Agency has been involved and the industry has been involved and there was the bemoaning of the cite-all requirements, but it puzzles me about this.

There was the regular suing in court to prevent any revelation of data to the public and the public was crying that they did not have access to the data. The EPA was saying they cannot have access to it because it is tied up in court and they are scared to be sued.

In light of all that, I am struck by your statement that your experience thus far has not revealed any compelling reasons for changing the law at this time.

My impression of problems we have been wrestling with with industry and you folks and ourselves and with public interest groups and so forth is that we have been wasting our time and have been misled by everybody in the field, or your statement that there is no need to change the law at this time is totally at variance with reality.

Would you mind sharing with me where you came up with this notion that we should not try to fix it?

Mr. TODHUNTER. I will share with you our thoughts on that matter.

One of the problems the Agency has had over time with the administration of FIFRA is that just when the Agency thinks it knows what it is doing, the law is changed again. This law has been amended and amended.

Our basic concern is that we are not sure until we have clearly identified a better way to do something that we should go in and change the law.

Until this administration has had a chance to implement and make what administrative fixes might be possible, should we do that? We will know better whether we need to fine tune it legislatively.

The problems in section 3 have more to do with industry's desire to protect their data which they generate than they do with the administrative functions of the Agency.

The changes in section 10 have more to do with the desire to protect what is felt to be proprietary information. That is one area where we feel that there may be a need for some legislative solution.

However, we do not feel that the one which is currently proposed is one which will necessarily remedy the situation inasmuch as industry would have no control over who has access to those data and they will not know.

The studies would not become available any more quickly than they are now under the Freedom of Information Act.

Mr. FITHIAN. Let me ask you and Mr. Gray this question.

The CSMA people are uptight about the California situation. They seem very, very fearful.

Are you of the opinion that if you do not exercise your arbitrator's role that it will somehow get solved? Is there a solution administratively to that one?

Mr. TODHUNTER. I think the situation which exists in California is one which may not necessarily serve as a proper model for what the rest of the States will do.

So, I am not sure, and the Agency is not sure, that to propose a specific legislative amendment to correct a problem which exists in a limited fashion is worth the statement that the States must now report to us and allow us to tell them whether or not the request is reasonable.

We would be more than happy to work with the States to help them to identify data requests, but it basically has been the position of this administration that the States are people who know what goes on within their boundaries. They have a better feeling for these things.

That is why under the special use registration and under emergency exemptions, we have given the States under this administration more authority and more leeway in defining their local problems. We do not live in the States.

Mr. FITHIAN. Let me switch over to the legal shop. We have been going through the court suit cases and so far as I know no data has been made available to the public interest groups because you have been in and out of court and so forth.

Mr. Gray, are we at the point where the public interest group which wants to get the data, like the toxicity studies or whatever it is that they want to get, that is, are we ready to say to them that the courts have run the case and we can make it available?

That is another need we have heard a lot about in the last 2 years.

Mr. GRAY. Could you repeat the last part?

Mr. FITHIAN. Are you now ready to say to the public interest groups "Yes, the courts have run their course and we can now give you the data that you have been asking for."?

Are we ready for that?

Mr. GRAY. In some cases yes, and in some cases no. There are still some court cases pending which prohibit us for the time being from releasing any studies that have been submitted by some of the companies.

We have a number of cases still pending at the appellate levels and in some cases they are still at the district court trial level.

With respect to other data, some of the court cases are over and we have, as I think you are aware, a petition pending before the Agency requesting an administrative option of the kind of protection that section 10 changes here will provide.

My understanding is that the administrator has that under consideration.

Once that matter is resolved, we will be able to proceed from there.

Mr. FITHIAN. The third area that we have been wrestling with is this. It has become quite subdued lately, but that the NACA concern of a couple years back about cite-all.

Administratively, have you ironed that out or have you worked out a system whereby you can take care of those continuing complaints without having to cite everybody's data rather than dealing with the cite-all controversy?

Mr. GRAY. The cases are still pending before at least three courts on the validity of the cite-all regulations. Several courts have said that indeed they are all right and they are permissible.

As to whether or not we have developed amendments to the present system that would allow some companies to do cite-all and others not to do it, I cannot say we have developed that.

Dr. Hernandez' letter said we were willing to look at that and we are looking at that.

Mr. FITHIAN. Are you of the opinion that without any changes in the law that you will solve that one administratively?

Mr. GRAY. If you are asking for my legal advice, there are some legal risks in setting up a new system which is rather different from the present system without first being told by Congress that we should change the system.

Mr. FITHIAN. Thank you.

Thank you, Mr. Chairman.

Mr. BROWN. Let me go over the same question one more time.

I am not clear with regard to the situation about the release of data. You have indicated that some are ready to be released and others are not and you are carefully reviewing the whole situation.

May I specifically ask if you are considering any changes in the existing Freedom of Information process which would have an effect upon the release of the data?

Mr. TODHUNTER. The Office of General Counsel is reviewing our Freedom of Information procedures. It is possible that as a result of that review they may propose changes which may affect what we are doing.

Mr. BROWN. That review is in process and you are not able to specify whether or not there would be any changes recommended or what the nature of the changes would be?

Mr. TODHUNTER. I am not privy to that review.

Mr. BROWN. Do you have an estimate of the time as to when it will be finished?

Mr. TODHUNTER. No, I do not. I am not privy to that information.

Mr. BROWN. I see.

Mr. Fithian?

Mr. FITHIAN. Would it be possible for the members of this committee to get that memo that is intradepartment as to how you are proposing to deal with this? You said you had a memo; did you not, from the General Counsel's Office?

Mr. TODHUNTER. No; I understand that the General Counsel's Office is reviewing our Freedom of Information procedures, but I am not privy to the process of the review or the time frame under which they are operating, nor any of their leanings in this matter. I do not know that.

Mr. FITHIAN. Would you expect in the administrator's office to get a written set of recommendations or observations from the General Counsel in the short while?

Mr. TODHUNTER. That is possible, but I am not the person who can answer that because I do not know what the work product is expected to be.

Mr. FITHIAN. Mr. Gray, could you answer that?

Mr. Gray, are you at work drafting something to lay out a series of options as to how we handle this problem to the administrator?

Mr. GRAY. Yes, sir. We are preparing a memo. We have prepared it, so far as I know, and our office has worked it out. It is final and it has been forwarded from our office.

Mr. FITHIAN. The reason I raise this is that obviously if we had this kind of memo it might help. There may be a complete solution in there and then we could write this law in a very different way, or maybe we could drop out section 10 altogether and not worry about it or do other things.

If we knew there was going to be an administrative remedy, we could do that. Before we write the law, we ought to have that proposal.

Mr. BROWN. We will try to maintain the cooperation with the Agency which we have had in the past and see if we can get that information. [Laughter.]

Mr. Todhunter, you made an interesting observation with regard to your position in support of maintaining the present law. You said you thought by the time the law was being understood and implemented, then the law was changed and that was detrimental to the continuity of your activities.

May I say that at times up here we have the same feeling about the personnel of the EPA. About the time we think they understand the law they are changed. They no longer seem to understand the law. [Laughter.]

Let me bring up perhaps a somewhat extraneous question and ask you to comment on it. It has been reported in the professional literature that the Agency is considering an application for approval of ferriamicide a derivative of Mirex which this committee has wrestled with for many years.

I am not sure whether it is to approve it or to approve an exemption for it or emergency use or what the situation is.

But I want to ask you if you would comment on the processes by which you will undertake to make a decision on this matter.

Mr. TODHUNTER. Yes, Mr. Chairman.

The Agency has received an application from the State of Mississippi for conditional registration of ferriamicide. That application for conditional registration is now under review in the Office of Pesticide Programs.

There are some outstanding questions which must be resolved before we can proceed further with that review. They have to deal primarily with whether ferriamicide and Mirex are one and the same chemical entity with regard to their technical and chemical properties.

Second, whether they are one and the same is a legal issue. That is something that has been referred to the Office of General Counsel. We have not yet received a written opinion.

Mr. BROWN. That is the same situation with regard to the Freedom of Information changes, then, right?

Mr. TODHUNTER. No; in this case I know that the request has been made and they are working on it. I expect to have a memo back at some point.

Mr. BROWN. I will not belabor it other than to express the view, I think, that the members of the committee share, that the same high standards of scientific judgment would be applied here as has been applied in the past. We trust that that will occur.

Mr. Panetta?

Mr. PANETTA. Thank you, Mr. Chairman.

I apologize for not being here earlier to hear the testimony of Dr. Todhunter. My questions may be repetitious.

I would like to ask how many present employees you have under your jurisdiction.

Mr. TODHUNTER. There are 1,150. That is our ceiling.

Mr. PANETTA. Following the budget recommendations, will there be a change in the manpower?

Mr. TODHUNTER. It is possible and that would depend on the outcome of the budget process which is ongoing.

Mr. PANETTA. Do you know how many personnel cuts are anticipated under the budget, assuming it is adopted as presented?

Mr. TODHUNTER. I can give you a range. Our range puts us at around or between 1,000 to 1,100.

Mr. PANETTA. Wait a minute. Did you say you have 1,150 under your jurisdiction?

Mr. TODHUNTER. Yes.

Mr. PANETTA. You anticipate a range in terms of reduction. But how many slots are you going to lose?

Mr. TODHUNTER. I cannot tell you precisely until I know what the budget is that is approved, but it is a range that would be in the range of 1,000 to 1,100 employees that would be slotted for as a ceiling.

Mr. PANETTA. So you may lose 100 slots?

Mr. TODHUNTER. Yes.

Mr. PANETTA. In terms of implementing the law as it exists today, can you do it with the personnel you have?

Mr. TODHUNTER. We are able to do it. Our management structure is not the most efficient, and we are working on that, but we feel we can carry forth the mission with which we are entrusted; yes.

Mr. PANETTA. Are you satisfied with the present situation as it exists now?

Mr. TODHUNTER. Which present situation?

Mr. PANETTA. In terms of how the law is being implemented and in terms of information released?

Mr. TODHUNTER. Freedom of Information?

Mr. PANETTA. Yes.

Mr. TODHUNTER. I cannot say that I am satisfied. That seems to engender such controversy and such dispute anytime we get into a situation like that. So, there is some underlying problem which must be addressed.

If it is a problem that can be addressed administratively, our basic feeling is that there may be strictures there because of the language of the statute.

Again, depending upon what happens in the General Counsel's office with respect to their review of the procedures, some of those things may be resolved and certainly having the Scientific Advisory Panel mechanism as a formal mechanism now, does provide an additional backstop. Hopefully, it will help boost the public's confidence in the procedures in what the Agency does.

Mr. PANETTA. May I ask counsel as to when they began to revise the operation or make administrative changes in terms of the processes?

Mr. GRAY. There are two different efforts that I am aware of that are ongoing. One had specifically to do with responding to the petition filed by NACA and also filed by 11 companies as a separate petition.

We have been working on that since last October, that is, it was filed in late October. We have been working on that and began our response sometime in November. It is a difficult area of the law. We researched it.

Mr. PANETTA. Is that pursuant to litigation?

Mr. GRAY. It is a petition subsequent to litigation, you might say, in anticipation of the demise of the litigation.

It is a petition essentially asking us to adopt, as a matter of agency policy, some of the prohibitions and restrictions and conditions on disclosure that this bill before us now would provide.

As I say, I believe our office is finished with that review and it has been sent on. It is not our job to make the decision, however, on this. We give legal advice.

As I see it, this is a policy question, in part. That part is finished.

We also have in the Office of General Counsel consideration under way of a number of proposals involving changes to our Freedom of Information Act regulations in a variety of areas.

One of the things that obviously needs to be done is to implement, by regulation, the changes to the 1978 act.

We have delayed formally changing the regulations because of the litigation that we have been involved in over the constitutionality of section 10.

Now that most of the courts seem to be saying that it indeed is constitutional, we think it is ripe to change the regulations.

However, we realize that we will not do it until it is more clear what will happen here in the Congress.

We do think some changes in the procedures just to reflect provisions of FIFRA since 1978 need to be made. There are a number of other changes that we were talking about, like the fee structure needing to be updated. There are some other statutes that have been passed since we last amended the regulations that involve disclosure of data.

So, we have an ongoing project to update the regulations there.

Mr. PANETTA. In terms of the status of the Freedom of Information, has that been referred on?

Mr. GRAY. No; I just received the first draft from the person primarily responsible for it.

Mr. PANETTA. Does that then deal with procedure under the Freedom of Information Act and how information would be provided?

Mr. GRAY. In general terms it does deal with that. It deals to an extent with the topics that this subcommittee deals with, that is, making conforming changes to the old regulations and bringing them up to date for the 1978 amendments.

Mr. PANETTA. Clearly there is a relationship between what is going on in the General Counsel's office which has reported out and the legislation before this committee; right?

Mr. GRAY. Yes.

Mr. PANETTA. I thank you.

I yield to Mr. Fithian.

Mr. FITHIAN. When you were petitioned by NACA on the reading room concept and this way out of the woods in terms of revealing data, and in pertaining to that, I have two questions.

What did you recommend to the Administrator? Also, in light of NACA's new position this morning, what actions will you now take? Or, does it become moot?

Mr. GRAY. With respect to the first question, I am hesitant to respond primarily because we are talking here about advice that our office has provided to the Administrator. It is a matter that is still before her. I am uneasy here.

Mr. FITHIAN. I gathered that. [Laughter.]

Mr. GRAY. You gathered correctly. [Laughter.]

Mr. FITHIAN. Dr. Todhunter, can you help him out of his uneasiness?

Mr. TODHUNTER. I have not read the memoranda yet. I know they have been transmitted, but I have not looked at them, so I am not in a position to help him out.

Mr. FITHIAN. Do you want to answer the second question, Mr. Gray?

Mr. GRAY. Would you repeat it?

Mr. FITHIAN. The second part was this. In light of NACA's new position, then what actions will be taken on that petition?

Mr. GRAY. I do not know what action the Agency will take. It tends to change the question that was proposed by NACA in the first place.

They originally requested that we take the action of adopting the early committee print version of this bill. They more recently requested that we treat the petition as being modified by incorporating this bill's section 10 changes.

I guess we would have to ask them whether they now intend to have us modify further to incorporate Dr. Early's testimony this morning.

So, I do not know if the petition is moot, but I think it is getting there. [Laughter.]

Mr. FITHIAN. Thank you, Mr. Chairman.

Mr. BROWN. Gentlemen, we are grateful for your testimony this afternoon. I hope this does not discourage you from further appearances, Dr. Todhunter. We basically are a very friendly group here. We are trying to do what is good for the country.

I do not think we have any more questions, but I would like to indicate to you that the work of the subcommittee would be greatly assisted if you, in working with our staff, could try to resolve some of the questions that you agreed to respond to within the next couple of weeks.

I think we are going to try to dispose of this legislation one way or the other shortly after that.

Mr. TODHUNTER. Thank you for the opportunity, Mr. Chairman, to present the Agency's views on this bill. I can assure you that we will be most cooperative with the staff of the subcommittee in this matter.

[The following information was submitted:]

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., March 9, 1982.

Hon. GEORGE E. BROWN, Jr.,

Chairman, Subcommittee on Department Operations, Research, and Foreign Agriculture, Committee on Agriculture, House of the Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: As promised when I appeared before the Subcommittee on February 4, I have looked into several questions you posed, and am providing the additional responses.

Question 1. Please elaborate on what incentives are available to industry to create new markets if industry does not have exclusive use protection for new use data.

There are several points to consider in response to this question.

(a) The most obvious incentive is the one that exists right now—the profit to be made in expanding into a market where there is a demand. Industry has never enjoyed exclusive use on new-use data, yet new uses have been developed where there was a profit to be made, i.e., sales would return the investment and produce an acceptable margin of future returns.

(b) In the minor use area, there is no reason to believe that exclusive use protection will encourage industry to spend the resources necessary to obtain registrations for a minor crop or for a minor pest on a major crop. The simple economic situation in this case is that the market will not return the cost of developing the data, and/or the potential liability associated with the specialty use is judged to be too high, whether or not that data enjoy special exclusive use protection. Registrants already are entitled to 15 years of compensation for data developed to support a new use pattern, so this information is protected right now and cannot be used freely by competitors.

We believe the minor use problem is better addressed through: The IR-4 program which develops data necessary to establish tolerances for minor uses; the Agency's minor use policy, which seeks to reduce data requirements to a minimum in order to encourage registration of minor uses; and the Agency's new crop grouping scheme, soon to be published, which will reduce data requirements for individual crops by extrapolating information from one crop to similar crops.

(c) Much of the information gathered by registrants to support a new use, particularly in expanding a use from one crop to another, is not required by or submitted to EPA, and it therefore would not be entitled to exclusive use protection. This would include information on the efficacy and phytotoxicity of the product. Therefore, exclusive use would not provide an incentive to develop a significant portion of the data typically developed to register many new uses.

(d) The basic "reward" for innovation in this country is the patent system. Congress has asserted the principle that 17 years is a justified period of time to enjoy special marketing rights for an innovative product. To assert in FIFRA that a manufacturer has not only an exclusive period of marketing at the beginning of the life of a new product, but also for additional new uses after the original period has expired, raises equity questions that the Committee should consider.

Manufacturers have the incentive to develop new uses as rapidly as possible under the patent system and the current FIFRA while the 10-year exclusive use period is in effect (or 15 years under H.R. 5203). One could argue that it may be in the best interests of the agricultural community to encourage new growth markets at the beginning of a new chemical's life in order to put new tools in users' hands faster.

(e) Finally, even if providing exclusive use for new uses would inspire innovation, we question whether that benefit would outweigh the administrative costs and associated slowing of the registration process. We do not believe it would. As we continue to emphasize, we see great complications for the registration and reregistration processes if exclusive use protection is expanded to new use data (please refer to Dr. Hernandez' November 17 letter and my testimony of February 4 for fuller discussions of this point.) This Administration is committed to speeding up turnaround times and streamlining the registration process. Simply put, we can't have it both ways; adding to the administrative processing costs of 3(c)(1)(D) is going to slow the whole system down. I don't think that will be in the best interest of industry, the Agency or farmers and other users.

Question 2. Could the 18-month implementation delay be waived if an applicant relies entirely on his own data?

We could expedite implementation of Section 3 in the case of registrants who are now blocked from the market because of the combination of cite-all and exclusive use. We believe this is the case that would demand immediate attention.

As for implementing the rest of the section in under 18 months, Dr. Hernandez outlined all the tasks that the Agency would be required to undertake in his No-

vember 17 letter to you. The time it will take to get ready for the new system will depend on how many resources we devote to those tasks. We suggested 18 months because:

(a) changes in regulations are required—which under FIFRA is a lengthy process given all the external and Congressional reviews required at both the proposed and final stages;

(b) the index is required to make it work in most cases, which will not be ready for a year; and

(c) we could continue to devote resources to the registration process and try to get our backlog down and to doing the implementation tasks if we had an 18-month lead time. If the Congress and the public would permit a moratorium on the Agency's receipt of registration and EUP applications for nine months, we could probably have our tasks completed and be ready for the switchover to the new system. I don't think it's a tradeoff that would be welcomed, and it's not one I would recommend.

Question 3. Can expedited procedures be adopted to allow certain categories of data to be released expeditiously?

This question would be better posed to industry, since you are asking whether there are types of data that do not typically contain trade secrets and that would not pose a competitive disadvantage if released. As you know, the Agency has suggested some new concepts on revising § 10 which I have shared with you, and look forward to discussing further in the future.

I hope these responses are helpful. Please let me know if I can offer any further assistance.

Sincerely,

JOHN A. TODHUNTER, Ph.D.,

Assistant Administrator for Pesticides and Toxic Substances.

Mr. BROWN. Our next witness this afternoon will be Ms. Jackie Warren, counsel for the Natural Resources Defense Council.

Ms. Warren, we apologize for keeping you waiting so long, but we do not have as many opportunities to interrogate the spokesmen for the Agency. So, we had to do that.

You may proceed.

STATEMENT OF JACQUELINE M. WARREN, COUNSEL, NATURAL RESOURCES DEFENSE COUNCIL

Ms. WARREN. Thank you, Mr. Chairman.

I have summarized our views on a one-page sheet at the beginning of my testimony. I want to state there are provisions in the current bill that we do support, which I have not addressed in the longer testimony.

I want to discuss some of those, but would ask that my formal testimony be inserted in the record.

Mr. BROWN. Without objection, so ordered.

[The prepared statement of Ms. Warren appears at the conclusion of the hearing.]

Ms. WARREN. We do support the change in section 3(c)(8)(D) that would provide direct appellate review of decisions not to suspend or cancel or restrict classification following the RPAR administrative review.

That makes it easier than having to go to district court first when there is a record of the Agency as a result of that process. It is available for appellate review.

We also support the inclusion of section 3(d)(1)(c)(ii) of specific groundwater protection considerations for EPA to take into account when registering pesticides in the hope that the kind of problems we have seen with Altocar on Long Island and with drinking water and NDVC in California could be avoided in the future if the registering authorities will simply consider that potential adverse impact when they first approve the registration.

We also support the addition of employee protection against retaliation provisions of section 12(a)(2) and the provision of deadlines for the adoption of guidelines and safe use of pesticides and safe working conditions.

We very strongly support the inclusion of section 16(e) of a private right of action for persons who are aggrieved by the misuse of the pesticide.

Dr. Todhunter questioned whether private right of action and the antiretaliation provisions are properly in FIFRA and wondered whether they might not confuse current authorities and remedies.

As a matter of fact, there is no private remedy against harm from the misuse of pesticides at the present time. The Supreme Court, and the courts in general, have consistently been saying that if Congress does not give you a private right of action to bring this sort of thing, you do not have it in the Federal courts.

I would urge you to consider supporting that.

In terms of the retaliation provision, those provisions exist in a number of statutes. The Toxic Substances Act has it and the OSHA statute has it. They are appropriately in the statute where the problem can arise.

There is not any generic statute that provides protection of workers as a general matter, so it is not a matter of confusing other remedies.

We strongly oppose the changes that are proposed in section 10. We have stated this previously. We are not advocating changes to section 10.

Our major dissatisfaction with the way section 10 as it presently exists is that it is not being implemented and that is different from what Mr. Gray said.

Because of litigation the implementation of the 1978 amendments has been held up. It is also quite clear that it is not clear whether the data is now going to be released.

We have serious problems with the Agency implementing a system of changes such as are in the proposed section 10 before they can enact it when clearly present law does not do that kind of a system in the same detail that is listed in the proposed amendments.

In my personal view I do not think that the current law provides for that kind of a system to be implemented.

We also oppose the proposed amendment to section 24 primarily for the reasons that other witnesses have stated and particularly the State of California which will be presented.

We also urge the subcommittee to restore to environmental and labor and consumer organizations the right, once again, to challenge EPA's pesticide regulatory decisions in hearings before the Agency.

I would like to speak to the issue for a moment. I was a witness at a previous hearing where that question was discussed by members of the committee. I did want to try to explain once again why we are asking for that.

Section 6(b) of the act and which there are amendments presently in the bill dealing with section 6(b), we think it would be appropriate to make a further change in section 6(b) since you are already considering it.

The present language says a person adversely affected by a notice of cancellation can request a hearing at EPA. That language should cover all persons adversely affected by the notice.

The committee reports on the 1972 amendments which puts that language into the statute make very clear that Congress intent to cover all citizens who believe themselves to be adversely affected by a pesticide regulatory decision.

From 1972-79 EPA interpreted that language as meaning exactly that—anybody adversely affected could have a hearing at EPA.

In 1979 EPA reinterpreted that language to mean that only registrants and users of pesticides who have an economic interest in the continued registration of pesticides were entitled to have a hearing at EPA.

Those are the only people who could be adversely affected by a notice of cancellation.

The result of that is that people who think that the notice went too far can have a hearing and if you think it did not go far enough or it is inadequately protective of the health and the environment, then you cannot have a hearing.

We believe that this reinterpretation of the words "adversely affected" has simply excluded the general public from meaningful participation in pesticide regulatory proceedings.

In our view, it simply is unfair to exclude members of the public from challenging the adequacy of the pesticide regulatory decision in hearings before the Agency while guaranteeing at the very same time the right of the pesticide producer and user groups to challenge the stringency of such decisions.

We do not believe the Congress meant to create such a discriminatory procedure when the words "a person adversely affected by the notice" were put into section 6(b) in 1972.

EPA did not think so either from 1972-79. The members of the public had this right from 1972-79. They do not have it now.

We believe that if the commitment of this subcommittee and of the entire Congress for public involvement in oversight of EPA's regulatory decisions is to be more than mere lip service, the right of the members of the public to stand in EPA's pesticide hearings should be restored.

It is not a hopelessly complex or technical issue. On the contrary, it is simply a question of fairness to assure that members of the public are once again included in the review and decisionmaking aspects of the pesticide registration process, we urge a one-word change in section 6(b).

Where the language now says "unless a request for a hearing is made by a person adversely affected by the notice" we would like you have say "unless a request for a hearing is made by any person adversely affected by the notice."

Then include some legislative history language to clarify that the reason for the change is to insure that members of the public and environmental groups and labor unions and any concerned citizen who feels adversely affected by a pesticide registration petition can have a right to a hearing at EPA.

With respect to section 10, we have been involved with other parties in an effort to reach some kind of a compromise and language, but we still have found that the proposed section 10 falls so far

short of achieving the objectives that Congress was attempting to accomplish in 1978, that we have to oppose it very strongly.

The language itself—before we get to the language, the question is whether EPA has the money to fund 10 regional reading rooms plus one at headquarters. Even though EPA in their testimony said they can implement that provision, I have strong doubts in the current budget-cutting climate.

Even if the funds were available, access to the reading rooms and the operation of the reading rooms remain problematical. It is not clear whether access to a reading room is going to be provided when someone shows up because of the requirement that the person who wishes to use the reading room stated in writing their affiliation and description of the data and so on.

There remains a strong likelihood that a person simply showing up may not be able to get in immediately.

This problem could pose a serious inconvenience to members of the public who have to travel some distance to get to the reading room at headquarters or at a regional office.

The second problem posed by the strict limitations on what may be copied is important. Under the present law the complete studies are theoretically fully available to the public.

As we all know, no one has received any of these studies yet. So, it is theoretical.

The proposed amendments would limit copying to charts, graphs, and tables containing statistical data while an earlier draft of the amendment also permitted copying of conclusions and executive summaries. Even this is now prohibited.

These limitations greatly diminish the utility of the data.

Although there are provisions for removing complete studies, what can be done with the complete studies seem to me to be hopelessly complicated and, because of the difficulties and ambiguities in the language, it is certain to have a chilling effect on people wanting to make some use of that information without running in violation of either the prohibition or disclosure or perhaps the very high monetary fines or completely barring them from further use of the reading rooms.

Another problem is raised by the different and apparently contradictory time periods that exist in section 10.

Wholly apart from the question of what criteria are going to be applied by the Administrator as to whether a person can remove data from the reading room, that decision is supposed to be made within 30 days.

Under section 10(c), the section entitled "Disputes," the Administrator is directed not to make available any data in which the confidentiality is disputed until 30 days after receipt by the owner of the data of the Agency's intent to release it.

In another section, section 10(d)(1) says that before disclosing any information in response to a request, the Administrator must provide up to 60 days for the owner of the data to identify portions that it claims to exempt from disclosure.

Section 10(a) says that those, that is, the identification of confidential data in substantiation is supposed to be made when the data are originally submitted.

It is the difference between 30 days initially and 60 days that is hard to figure out exactly when the public would be able to get access to that data the way it is presently written.

Another problem stems from the fact that without any criteria for the Administrator's determination of whether data may be removed by particular applicants, obviously the intention is that denial only occurs in those cases where a competitive disadvantage will be the result.

But it does not say that anywhere and, hopefully, it would say something about that in the report. But the decision then is final and not subject to judicial review, which means that persons who are denied, and we perceive we will be denied as often as anyone else, would be completely deprived of any remedy against capricious denials.

So, we oppose that in that provision.

One of the most serious problems in section 10, beyond the others, involves the penalties for improper disclosure, since what is improper disclosure remains ambiguous.

Deliberate misuse for commercial advantage should be subject to civil and criminal sanctions.

However, proposed section (d)(2)(G) provides that the information in the documents and the documents removed from the reading room shall not be disclosed or made available in any manner by the borrower to any other person.

That section also contains a blanket provision on reproduction in any manner of any material borrowed from the reading room.

Apparently the only material that may be freely used in administrative, judicial, or legislative, or other proceedings or utilized in any other manner are the charts, graphs, statistical tables, and notes taken from the available studies.

It is not even clear whether executive summaries and conclusions may be copied and quoted verbatim. The language seems to suggest not, because that would be reproduction in some manner of the material which is not described elsewhere as being available, which would be drafts, graphs, and charts and so on.

Furthermore, the debarring from all further access of not only the person who transgressed what I consider an ambiguous order, applies to every one that person represents. The whole NRDC might be barred and a whole labor union.

If you are going to have that heavy a sanction, then the lines have to be very clear so that people can see and understand exactly what it is they cannot do.

I do not believe this language accomplishes that. In fact, I perceive this as creating insurmountable obstacles to meaningful public access and use of the health and safety data.

I realize also that you recognize the fact that there is some situation where complete studies must be turned over, for example, in litigation or adjudicatory proceedings. It is not going to be adequate to say.

"I have seen the study and this is what it says."

You provided for that. If the parties' access to the data is found to be necessary in order to guarantee full participation in the hearing or litigation, that is fine, but you have not said, how, when, or by whom the determination of necessity is to be made.

That seems to me to be a very serious shortcoming.

As we said in our earlier testimony, the 1978 amendments to section 10 were the result of a lengthy debate. It was a carefully weighted effort to try to accommodate the concerns of the manufacturers and the public regarding data disclosure.

It is apparent from the debates and the committee reports that one of the principal objectives in enacting the provision was protection of public health.

The disclosure provisions recognized that the public does have a right to see and evaluate those health and safety data and has an important role to play in evaluating and insuring that the decisions EPA makes are based upon good scientific bases.

Given the current and projected cutbacks in the EPA manpower and resources, it seems to me that this public input is more than ever necessary.

It is for these reasons that we strongly oppose the enactment of the section 10 amendments.

That is all I have to say, Mr. Chairman. Thank you.

Mr. BROWN. Thank you.

Mr. Wampler?

Mr. WAMPLER. Thank you, Mr. Chairman.

Have you or any member of your organization ever been denied access to any health or safety data by EPA?

Ms. WARREN. We have been because the 1978 amendments have not been implemented.

Most of my prior involvement with health and safety information before EPA involved participation in cancellation hearings where the data was made available because by law they were made available in the context of those proceedings.

But we have been denied information in the past. We have requests pending at the present time. It is up in the air whether the data will be released.

Mr. WAMPLER. This morning Mr. Panetta had a colloquy with Mr. Kirk Johnson of the Center for Science in the Public Interest. I had to leave the room to go to another hearing.

But it occurred to me—and if I understand the situation correctly—that the Food and Drug Administration has a procedure in place where it is possible for the industry groups to provide executive summaries on health data to groups that have an interest in the data rather than releasing all of the data.

I was wondering what your reaction would be, for example, if industry groups were willing to give you, or anyone else who has a public interest, an executive summary on the health data.

Then, once having had access to that, if you felt like that was not fair and if you needed more information and more detail, maybe there could be some procedure that you could appeal that, for example, to the Scientific Advisory Panel, to see if, in fact, it could be handled that way.

Are you familiar with that procedure?

Ms. WARREN. Yes; I have been working with groups trying to get that changed so that the full data will be made available to the public.

But that is a provision of the Food and Drug Administration that was enacted prior to the change in FIFRA. The change in FIFRA

came after the 1976 inclusion of a comparable provision of the Toxic Substances Control Act.

Summaries are not adequate. Our scientists tell us that they cannot evaluate whether a study was done correctly and what the basis for the conclusions that are in the conclusions and summary really were unless they can see the full description of the study.

And, in fact, if it comes to the underlying data, including the sides—I am an attorney. I have worked in this area for the last 8 years. They have repeatedly had situations where we have had the full studies.

One of the problems is that if EPA had a good history of registering pesticides based on good studies, that would be one thing.

But that really is not the case. EPA does not know whether many of the pesticides registered are based on sound studies. Something like two-thirds of the registrations or one-third of the registrations are based on IBT data which has been called in serious question.

It is that insecurity about the validity of the data that underlines the registration and makes us want to not see what the submitter concluded with respect to it, but to take what the study itself is. Summaries do not do that.

I am not sure that referring the matter to the scientific advisory panel would solve the problem, either, because the panel does not have all the expertise on it that it should have.

There is a certain ideological cast about the things in the administration today more than it was in the past. I am not sure that we would be confident that the review that was given would be fair unless we could see the basis for their conclusions.

In addition to that, there are so many kinds of tests submitted. You would need representation on those panels of every kind of discipline.

In the past there have been examples of the committee trying to deal with questions without. For example, there is the one of the DBCP problems that had to do with ground water contamination. There was no expert at the SAP in that area. They also did not have a mutagenist on the panel.

I am not sure that is a good solution to the problem.

Mr. WAMPLER. It would be fair to say that nothing short of complete and total access to all data would satisfy your point of view; is that correct?

Ms. WARREN. I think I would want to be able to see all of the safety data; yes, and have a scientist that I respected and felt confident about to tell me that it was a good study.

Mr. WAMPLER. The horns of dilemma you see clearly. There are those that you feel should have no access to it. They apparently have implicit trust in EPA to administer the law as Congress passed it.

Then you have groups like yourselves who feel you should have total access. Somewhere in between those two points of view, we are trying to resolve this thing.

I can see both points of view, but obviously both points of view cannot be sustained. We have to find something in between.

Ms. WARREN. I understand that. But we went through this in 1978 and thought we had reached something that everybody could live with.

We do not know whether we can live with it or not because it has never been tried. From my point of view I would like to try what Congress felt was a solution in 1978 and see whether it works before we assume it is not going to work. Only 3 years ago we thought it would work.

Then if it does not work, then change it, but it seems to me that we do not know whether it is going to work or not. We have not tried it.

Mr. WAMPLER. I do not offer this as a defense for the Agency because they are capable of speaking for themselves. But if the Agency could have taken the time and resources that they spent in court in the Agency trying to resolve procedures, then we could have made better progress.

But it is your right and the right of any other person if they have a legitimate interest to bring suit.

Ms. WARREN. The suits under the disclosure provisions have not come from the environmental side. They have been industry.

Mr. WAMPLER. I am talking about anyone who had a legal right. It is a tremendous amount of time and resources. The Agency has to spend this defending. I am not questioning anybody's right.

But they have a limited number of manpower available. This is part of the problem.

I hope you see where our problem is. We have two diametrically opposed points of view here. We have to find some resolution. Thank you, Mr. Chairman.

Mr. BROWN. Mr. Fithian?

Mr. FITHIAN. Thank you, Mr. Chairman.

Ms. Warren, I want to clarify your concern about not having standing—maybe I misread what you said.

You use interchangeably standing and administrative hearings and the right to sue in court. Is that an accurate reading, or can you sue in court but you cannot get into the administrative hearings?

Ms. WARREN. After the RPAR decision was made, EPA said that they are registering this one use and canceling this other use.

If the registrant is unhappy with that because they wanted both uses to be registered, then they can say that they want an adjudicatory hearing at EPA under section 6(b) and they can get it.

However, if we, who also participated in that RPAR rulemaking process, say: "We think you should have canceled both of those," then we cannot ask for a hearing. It is only if you think they did too much.

If you did not think they did enough, you cannot.

Mr. FITHIAN. Yes; I understood that.

Ms. WARREN. It has nothing to do with the right to sue. We can go back to court and sue EPA for not canceling the second one and make the case there. If we win, EPA would be directed to reconsider or hear the arguments.

We would like to be able to present our arguments in the first instance in the hearing that EPA will have. If the industry asks for

it, we can intervene. If the industry does not ask for it, we cannot ask for it ourselves.

Mr. FITHIAN. Let me direct your attention to the judicial review section, section 8, which is proposed to amend section 16 of the law. The proposed change would read as follows:

Any person claiming to be aggrieved by misuse of a pesticide may bring suit in the U.S. District Court having jurisdiction of the parties for damages, equitable relief, and reasonable attorney's fees and costs, including expert witness fees.

Would that not open up a floodgate of suits and Federal fees to attorneys and things of that nature?

We would bypass the State courts, but I do not know whether that is a good idea or not because I am not a lawyer. But passing that by, I think given the tendency of our society—if I can step aside from this case—to sue now has become endemic.

It would seem to me that there would be a tremendous temptation to bring all kinds of suits. I am not talking about legitimate concerns that you have raised here and that is, how you get access and how you get standing and so on.

I say that I am deeply troubled by this proposal. I would like to know what your reaction is to the language. If you have the bill in front of you, it is on page 46

I wonder if you would not support either deleting that in its entirety or making some radical changes there.

Ms. WARREN. I read this provision as a tort action provision for people who have been harmed by, for example, aerial application.

This is a situation which the courts have always provided access to injured parties. But in some situations involving the use of pesticides you may not be able to reach both parties in the State court because you cannot get jurisdiction over the injuring party.

If you could get into the Federal courts on diversity jurisdiction, then you need the private right of action to do that.

Maybe the only way you can reach the person who damaged you is this way.

Or, if you need to reach back beyond the immediate source of the damage, for example, to the manufacturer, you would not be able to do that unless you get jurisdiction in the State court.

Apparently this has been a serious problem for farmworkers. They have not been able to get compensated for real personal injuries that they have suffered and the medical expenses.

I do not see a plethora of suits and the floodgates opening as a result of that. This is a private right of action which has been tried. They want to reach back and get compensated for their injuries. They have been foreclosed by the courts because the Supreme Court is saying that unless Congress wants to allow you to use the Federal courts for this use you cannot and the private right of action will not be given.

Congress has given it or not given it in very different types of ways. This has been over the passage of time and people have more or less focused on it.

But the action is in some statutes and not in others with no apparent reason for the differentiation.

It seems to me there is a real need to give people who are injured some courtroom in which they can go.

Mr. FITHIAN. I will not argue with that. That is not where I am coming from.

I am troubled by the jurisdiction which you have addressed. But I am also troubled by lines 17, 18, and 19 on page 46 about attorneys fees and equitable relief and expert witness fees and so on.

It seems like a blank check invitation to the legal proceedings.

Ms. WARREN. There are ways to word it so that it is entirely at the discretion of the court. Other statutes——

Mr. FITHIAN. One can always sue for any amount, including legal fees and so on. But to write it in the statute, I wonder.

Ms. WARREN. To get Federal funds for attorneys fees? I do not see that here. I see that you are authorizing the court to award attorneys fees to injured parties.

Mr. FITHIAN. The court could award that anyway.

Ms. WARREN. Sometimes they do and sometimes they do not. It is a question.

Mr. FITHIAN. We cannot mandate the judges to do anything.

Ms. WARREN. But some courts will not do it at all if they have not seen it in the statute that they are authorized to do it.

This is trying to make it certain that if they choose to, they may.

Access to the forum is the most important part of that. Attorneys fees are a big problem when you are talking about farmworkers.

So, I think it is a reasonable provision. That is not an award of Federal fees, as I understand it. These suits would not be against the U.S. Government, particularly. They would be against an applicator or a company or a manufacturer and someone who misuses a pesticide in violation of their registration.

Mr. FITHIAN. Thank you.

Thank you, Mr. Chairman.

Mr. BROWN. Ms. Warren, we thank you for your testimony.

Our next witness will be Mr. Thomas McGarity, University of Texas Law School.

We are happy to see you. You may proceed.

STATEMENT OF THOMAS O. MCGARITY, PROFESSOR OF LAW, UNIVERSITY OF TEXAS SCHOOL OF LAW

Mr. MCGARITY. Thank you, Mr. Chairman.

I am pleased to be here today to speak once again to the issue of the trade secret status of health and safety testing information.

Much has been said already, so if it is possible, I would like to submit my written testimony for the record and be as brief as possible.

Mr. BROWN. Without objection, your entire statement will be inserted in the record.

[The prepared statement of Mr. McGarity appears at the conclusion of the hearing.]

Mr. MCGARITY. I want to address one concern of Representative Fithian. At the very end of the interchange of Ms. Warren, the fact of the matter is that attorneys fees are not awarded to private plaintiffs in American jurisdictions unless there is a statutory provision for that and the judges do not have discretion to do so. That is the so-called American rule as opposed to the British rule.

That was reaffirmed by the U.S. Supreme Court in the Allasco Pipeline case. So, if there are to be attorneys fees at all for farmworkers, they would have to be provided for in the statute.

Going on to health and safety data, I came to talk about that. I would like to address particularly the potential that amending FIFRA at this point in time would have for costly and time-consuming litigation.

Dr. Todhunter testified that a legislative solution, he thought, was probably necessary. I agree with that. It is necessary and it has been necessary since 1972 and perhaps prior to that time.

That legislative solution has been enacted in the FIFRA amendments of 1978. There the contending forces that are at play here were at play in 1978 and the resolution of that was that health and safety data with three well-defined exceptions which were aimed at protecting industrial processes and quite legitimately so, in my opinion, the health and safety data were to be made public.

That is what Congress decided in 1978. Numerous pesticide companies have decided to appeal this decision of Congress. They have gone to a higher authority, namely, the courts, their contention being that section 10 of FIFRA, as amended, is unconstitutional.

The courts have not surprisingly rejected that notion. It is simply beyond me how the contention has been made, but it has been made. The fact that an injunction, or preliminary injunction, will almost always issue in such a situation means that the data has not been disclosed.

Since the value of the data, whatever it is, is asserted will be lost if the data is released anytime, the courts are particularly sympathetic toward issuing a preliminary injunction.

This is precisely the wrong time to amend the statute. A good deal of that litigation is now coming to rest.

As I laid out in my testimony, the history of FIRA, and particularly on data and data compensation is that Congress amends the act.

We have 3 years worth of litigation. Congress amends the act just as the litigation is coming to an end. We have 3 years more of litigation. Congress amends the act. We are never catching up with ourselves.

I think if we just let the statute come to rest the courts, I think, would by and large, and especially the appellate courts, have interpreted the statute correctly and implemented the congressional intent.

What we need to do now, I think, is simply get down to the business of administratively implementing a statute and allowing some of these health and safety studies to be examined by public interest groups and scientists and representatives of farmworkers and so on.

There are severe penalties written into the statute as it exists for knowingly using this data to aid in the registration of a competing pesticide.

That applies both here in the United States and, of course, we have a 10-year exclusive use period. But it also applies in foreign countries.

That I would have thought was the bargain struck in 1978 and a heavy penalty was there for aiding in the obtaining of this data to be used overseas.

I suggest that we let the Agency start releasing some studies and let us see if all this competitive harm that we have been told about will occur.

My studies indicate that is not likely to. I have not seen a good representation that large markets would be lost overseas.

One reason for that, I think, is that as a practical matter and one can debate the merits of this back and forth, but not as much as required in the Third World to register a pesticide. So, you really do not need studies of the sophistication that are being produced in terms of the state of the art right now to get a pesticide registered over there.

So, it is conceivable that some market may be lost there. If it is, I would expect that it is more than made up by the 10 years of exclusive use and the 10-year monopoly that a company has in the United States.

Of course the markets are very large there as well.

With respect to Representative Fithian's Scientific Advisory Panel proposal, and I think Mr. Wampler raised it also, I will predict that if you enact that into the statute, then we will have litigation over whether the Scientific Advisory Panel was right or wrong in allowing studies. There will be another 3 years of litigation on that point.

In fact, what I have attempted to do in the latter half of my prepared testimony is this. In the first half I tried to set out the inconveniences of the reading room proposal for people who actually would like to see the data. They might want to look at the slides if someone is a pathologist or a scientist.

In the second part of my testimony I have tried to set out, as is my penchant as a law professor, a hypothetical situation.

At each point in the situation which I have an editor of a magazine trying to see the data and at each point where the litigation might arise, I mention it.

I will leave it to you to read through the hypothetical situation, but the fact is that the potential in amending the act once again is for another 4 years of litigation after which we are no further along the road than we were before.

I expect that at the end if the claims, frivolous or not, are rejected by the courts then we will be right back here in Congress.

But the fact of the matter is that as Mr. Wampler pointed out, we have two interests involved and they are not likely to be reconciled.

I will stop there and ask for any questions you might have.

Thank you.

Mr. BROWN. Thank you.

I read through your prepared statement, and it makes a very strong case.

I have this question. You have asserted that our efforts to amend the law would merely lead to another 3 years of litigation. You heard the testimony from the Agency that they are currently engaged in reviewing their regulations with regard to the application of the Freedom of Information Act.

Do you think there is any possibility that this could go on for another 3 years also?

Mr. MCGARITY. The regulatory solution? I would not put it at all past the Agency to take 3 years to come up with final regulations under the Freedom of Information Act.

The last group, as I recall, took on the order of 3 to 6 years to promulgate and, of course, the regulations under section 3 of FIFRA have taken an enormously long time to work out.

As the law is written right now—and I stated this in my testimony—I think that the whole procedure that is going on at the Agency is unlawful as the statute is written today.

The requests for data that have been pending for 3 years now that the injunction has been lifted, I think the Agency really only lawful response to that has to be to now give over the health and safety data.

Mr. BROWN. Even a distinguished law professor's idea of what is lawful or unlawful is really not binding until a court establishes it.

Mr. MCGARITY. Yes; absolutely. What will happen is this. If, for instance, the Agency decides administratively to not make the data available for some reason, I expect then we will find that the lawsuits from the NRDC and the other side will go on.

Mr. BROWN. It could go on for 3 or 4 years?

Mr. MCGARITY. Yes, it is quite conceivable.

Mr. BROWN. I think we have been aware of the consequences for litigation. I thought we could devise a scheme sufficiently acceptable to both sides and then it would not require litigation.

Basically litigation only occurs when the two parties are not satisfied that at least some minimal response to their own interests is being met.

Unfortunately it appears—and your own statement adds to that—that we have been unsuccessful in reaching that ideal state.

So, I am reconciled to that but I am not quite sure what is going to happen afterwards.

Mr. MCGARITY. From my reading of the history of the 1978 amendments, it looked like you had reached that point. Then the pesticide companies decided that your solution was unconstitutional. They upped the debate to another level.

As I listened today and I have read the legislative history of this, and I have read it back to 1972 and every hearing that has gone on, I get more and more depressed. [Laughter.]

Mr. BROWN. You should be in Congress. [Laughter.]

I have no further questions. If we do have some additional ones, I would like to address them to you in writing.

I appreciate the study you have given to this issue.

Our next witness is Mr. Tom Hecht, National Coalition Against the Misuse of Pesticides.

STATEMENT OF TOM HECHT, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. HECHT. Thank you, Mr. Chairman.

I would like to thank you for the opportunity to testify again this afternoon on behalf of the National Coalition Against the Misuse of Pesticides.

I want to make my remarks very brief and would ask that my prepared statement be inserted in the record.

Mr. BROWN. Without objection, so ordered.

[The prepared statement of Mr. Hecht appears at the conclusion of the hearing.]

Mr. HECHT. Let me respond to something that was raised by Mr. Panetta earlier this morning.

There was an extensive colloquy about the possibilities and hypothetical economic injury to the industry if the amendments to section 10 were not approved by this committee.

I would like to stress once again that there has been no hard evidence of that to date. But we are not without data.

The U.S. Food and Drug Administration has conducted a study not concerning the release of pesticides, but of other test drugs in comparable settings and have concluded that both the patent protections and international treaty arrangements and market considerations really precluded any serious economic injury.

That study is entitled, "U.S. Food and Drug Administration Supplemental Analysis of the Impact of Disclosure of Safety and Effectiveness Data on Foreign Markets of U.S. Multinational Firms."

With your permission, Mr. Chairman, I would like to submit that study to the subcommittee for its consideration. I think it has some very excellent conclusions. It lends a certain amount of concreteness to the discussions of the economic impact which I think is useful.

Mr. BROWN. Without objection, so ordered.

Mr. HECHT. I refer you to Mr. McGarity's 1980 Harvard Law Review article which I believe was admitted into evidence as part of the record earlier this summer in which a number of other studies of similar conclusions were analyzed.

As you know, the coalition has consistently opposed the present attempts to amend sections 10 and 24 of FIFRA. We have detailed our concerns in a document circulated to each member of the subcommittee.

That document argues against the amendments to section 10 because it first creates an additional monitoring function in 10 regional areas with full staff when we have no idea whether the EPA's budget will sustain that pressure.

Second, it creates an elaborate screening mechanism of who gets into the reading rooms and under what circumstances, but establishes no control or judicial review of that decision by the Administrator.

It restricts, we think, unduly, the use and dissemination of non-trade secret data. What we are talking about in the reading room restrictions is not trade secret data. That is not disclosed by what we are talking about that is previously disclosable nontrade secret material onto which we are now adding a series of restrictions.

Once one gets into the reading room, the proposed amendments contain no time limits for disclosure of data. And given the testi-

mony that we heard both from Mr. McGarity and from the EPA itself this afternoon, I am not at all confident that that data even if one is in the reading room, would be forthcoming.

Also, I think the draft creates considerable confusion about the application process. It is not at all clear whether or not one has to apply for a reading room card each time when one approaches a new data and each time when one has a request or whether one gets permanent approval.

Nowhere in the statute as proposed is there clarifying language.

The document that we presented you before argues against section 24 just briefly because it restricts State ability to gather data in order to regulate at a time when we think States may be the only ones in a position to do any kind of effective regulation.

I am sure there will be more along those lines in the State of California when they testify.

The only other issue that I wish to address is the proposed private right of action described in section 16 of H.R. 5203.

It is our understanding that some committee members have expressed reservations concerning this proposed amendment to the act.

Without going into the merits of any specific proposals, let me give you some brief idea of the basis of the coalition's support for section 16.

It is really an inescapable reality of our times that both the Federal and State regulatory agencies will be under very severe financial pressure.

Russell Train, the Administrator of the EPA during the Nixon and Ford administrations, estimates that by this June the EPA budget will be cut by some 60 percent and rather devastatingly notes that as of this June, he estimates that 80 percent of the headquarters staff here in Washington will have quit and have been fired and have been demoted or been downgraded.

Parenthetically, I think it would be useful to have Mr. Train's analysis included in the record as it was published in Tuesday's Washington Post.

I request that be done with your permission.

Mr. BROWN. Without objection, that will be placed in the record at this point.

[Material supplied follows:]

(Washington Post, Tuesday, February 2, 1982)

Russell E. Train

The Destruction of EPA

The Environmental Protection Agency is rapidly being destroyed as an effective institution in the federal government. Current and planned budget and personnel cuts, if continued, will inevitably reduce the agency to a state of ineffectualness and demoralization from which it is unlikely to recover for at least 10 years, if ever. While some may greet this situation with enthusiasm, I am convinced that the business community, among others, has very little to gain and a great deal to lose.

I see EPA's mission as a critically important one. I am convinced that, in the long run, our free enterprise system can only prosper and grow within the context of adequately protected public health and environment. I am also convinced that responsible business leadership knows this and asks only that regulatory requirements be reasonable, cost-effective, have an adequate scientific basis, and be fairly and uniformly enforced.

Corrected for inflation since 1981, President Reagan's expected 1983 budget request for EPA will represent a reduction of approximately 45 percent. Administrator Anne Gorsuch has reportedly been working on 1984 numbers of \$700 million, or a cut of 61 percent. EPA's research branch would be cut by two-thirds, far more than any other basic research program.

In the personnel area, the cuts are equally drastic. If Gorsuch is allowed to carry out plans that have been circulating within the agency for some time, by this coming June—one year and four months after the Reagan administration took office—80 percent of EPA's headquarters staff will have quit or been fired, demoted or downgraded.

It is hard to imagine any business manager consciously undertaking such a personnel policy unless its purpose was to destroy the enterprise. Predictably, the result at EPA has been and will continue to be demoralization and institutional paralysis. Attrition within the agency is running at an extraordinary 2.7 percent per month or 32 percent a year.

From an administration that quite rightly emphasizes the need for good management, what we are seeing at EPA is its very antithesis. Permits that businesses need do not get issued. Required rules and regulations do not get promulgated. Enforcement has ground practically to a halt. The most competent, technically proficient, professional staff have either already left or are looking for jobs. If one believes that effective environmental protection is essential it is tragic. If one is not necessarily an environmentalist but believes that our environmental programs need to be managed efficiently, scientifically and less burdensomely, the current situation is equally disastrous.

Congress and the courts will effectively impede the ability of the administrator to bring about substantial change by administrative action alone. But they will provoke an upsurge in lawsuits and more decision-making by confrontation. While adversarial approaches to conflict resolution seem to be deeply ingrained in American society, there have been encouraging signs lately of growing appreciation of economic realities within the environmental community and a greater environmental sensitivity on the part of the business community. A return to the early days of polarization benefited no one.

Many of EPA's difficulties over the years can be traced to the fact that Congress loaded the agency with far more statutory responsibilities within a brief period of time than perhaps any agency could effectively perform. Surely, those problems can only be compounded by drastically reducing its resources while its responsibilities remain the same or grow. When EPA came into being in 1970, it took over the air pollution, water pollution, solid waste, pesticide and radiation programs scattered around the federal government. Since then those programs have been broadened and improved, and Congress has added major new responsibilities—including the Toxic Substances Act, the Safe Drinking

Water Act, the Noise Control Act, the hazardous waste control program, and Superfund. These are not hangovers from the concerns of prior generations. EPA has been on the frontier of today's concerns, and there is every indication in the polls that environmental protection remains high on the public agenda.

Environmental protection needs are not going to lessen if EPA becomes ineffectual. The Kepone problems and the Love Canals will continue to crop up from time to time. Unless the public has reasonable confidence in the public institutions charged with responsibility for handling such problems, there is real danger of a backlash developing against business. The pendulum will swing once more and in even more violent oscillations. EPA will be forced to react and will do so without adequate staffing and with a reduced research base. Business needs greater stability and predictability of policy, and for that it needs a credible EPA. The tendency of our political system to ignore the need for reasonable continuity in institutions and policies is one of its most serious failings.

As one who served two Republican administrations from 1969 to 1977 and who voted for President Reagan, I must record my profound concern over what is happening at EPA today. The budget and personnel cuts, unless reversed, will destroy the agency as an effective institution for many years to come. Environmental protection statutes may remain in full force on the books, but the agency charged with their implementation will be a paper tiger.

The writer, president of World Wildlife Fund-U.S., was administrator of the Environmental Protection Agency from 1973 to 1977.

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Mr. HECHT. Those kinds of cutbacks in budget funding and those kinds of cutbacks in terms of staff capability are anticipated in a wide variety of State agencies and particularly those charged with the enforcement of pesticide regulations.

I think that obviously does not bode well for Agency enforcements of the provisions of the act, either at the State or Federal level, notwithstanding the good intentions of State and Federal administrators. I am sure they are trying to do a good job.

There simply are too few resources to do the job. The October 1981 GAO Report on Pesticide Enforcement, 1975-80, suggests that even before massive budget cuts, the viability of the enforcement mechanisms under the act was open to very serious question.

I think the attractiveness of the proposed section 16 in this particular climate is that unlike the current act it allows victims of pesticide abuse and victims of pesticide misuse the opportunity to challenge FIFRA violations directly in court and does not require extensive Federal or State enforcement machinery.

Further, through the attorneys fees provision of section 16, I think it encourages participation of the private bar in those matters rather than the public interest attorneys and legal services attorneys. That future is uncertain also.

I understand that the attorneys fees provision in particular is one of the more controversial aspects of section 16. But I think one cannot create rights without also creating access to them.

One cannot play with rights without remedies.

This is a system, that is to say, the use of attorneys fees, which Congress has adopted now in some 90 other Federal statutes.

That similar kind of provision is included in the Minimum Wage Law. Indeed, we now provide attorneys fee compensation to small businesses for legal expenses incurred in challenging arbitrary government regulation.

It is a system we ought to extend to victims of toxic pesticides to people unduly exposed to violations of FIFRA.

In short, the provisions of section 16 allow the act to become self-enforcing and I think that is its real strength. It is controversial, perhaps, but it is a real strength particularly in this climate. That is the core of the support we give to section 16.

I urge you to look at that provision and I urge the members to take that seriously. I think we are in a climate when this may well be the kind of model going into the 1980's under financial pressure in which we can retain the advances we have made in the health and safety regulations without at the same time adding to either State or Federal bureaucracy.

One final note. The coalition would like to be on the record for strongly supporting NRDC's position on the 6(b)(ii).

It is essential to effective public participation in this complex arena.

Thank you very much.

Mr. BROWN: Thank you. [Laughter.]

Mr. HECHT. I understand this problem with that. I listened attentively as he questioned Ms. Warren.

The comparable provisions in the Fair Labor Standards Act or the Farm Labor Contract and Registration Act or now the Equal

Access to Justice Act has really not created the flood of litigation that Mr. Fithian anticipated.

Interestingly enough, there are ways of modifying those attorneys fees provisions, as both the House and Senate have done, in the Equal Access to Justice Act.

They include a variety of provisions which grant the court the power to award fees if the defendants position was substantially unjustified and outside the suit. That is in the language there.

So there are possibilities. As the process continues, we certainly are willing to play with a variety of language and possibilities to see that this kind of right be included in the act.

Mr. BROWN. Mr. Fithian?

Mr. FITHIAN. Thank you, Mr. Chairman.

I have a comment. Some time back we got a bulletin in the mail. I think it was from NBC. They did a white paper with the comparison of Japanese society and the American society.

It talked about the basic differences in the societies. One of the striking things was the summary statement that they made that they are a society of consensus and we are a society of contention.

They used a number of lawyers we produce versus the number of scientists we produce and the number of lawyers Japan produces versus the scientists.

Then they went into a startling statistic about the extraordinary growth of lawsuits in the country.

I am reminded of the actual incident that happened in a classroom where a third grader, when the teacher turned to punish her for something, piped up and said:

"If you do, my dad will sue you."

I do not want to deny any action in this field that is available in many other fields, but I have a strong and growing sense that we are getting this society about as entangled with lawsuits as it can afford.

I have a sneaking notion that that fits into lots of different things, like rates of productivity increases and other things.

I have this sneaking suspicion that we might one day run the whole ship aground and not just because it is in FIFRA but I think philosophically there are some problems with using the engine of the Federal Government for this.

It is a powerful thing. It continues to promote the propensity for someone to sue somebody.

I fault industry as quickly as I do the other side. They have been suing the EPA forever and essentially making the 1978 act amendments unworkable.

So, they have had to live with the product of their own doing. I do not feel sorry for them.

But I do not want to contribute any more to this propensity to drag FIFRA up and down the halls of the courtrooms of the United States. I believe that is what it would do. I do not know what is causing all the suits, countersuits, and lawsuits and so on, but something is.

I will take your word for it if you say it did not cause a flood of suits with regard to another matter, but the sum and substance of the total picture has lead to that.

Mr. HECHT. Yes, I understand that.

The alternative, though, at this particular juncture is that we have an act for which there may be no enforcement. It seems to me that our choices are difficult.

Mr. FITHIAN. You mean never win?

Mr. HECHT. No, for violations of FIFRA of this particular act there are substantial numbers of people who, if this is not included, will have no remedy given the very slim likelihood of effective enforcement by either the Environmental Protection Agency or a comparable State agency.

Mr. FITHIAN. Or the courts?

Mr. HECHT. We cannot get into court in a variety of situations for violations of FIFRA. There are questions of jurisdiction and service of process and there are complications.

And, of course, a perpetrator could violate any number of provisions and in State court and in tort and common law, there may or may not be conclusive evidence of an actionable harm.

As it stands now, the restrictions of the act essentially are only enforceable by the EPA.

Mr. FITHIAN. Thank you.

Thank you, Mr. Chairman.

Mr. BROWN. You see the problems we have when we elect nonlawyers to Congress? [Laughter.]

Mr. HECHT. It is a breath of at least, I was going to say, fresh air, but sometimes more biting wind. I think it is healthy.

Mr. FITHIAN. Thank you.

Mr. BROWN. Thank you, Mr. Hecht, for your testimony.

Our next witness will be Ms. Maureen Hinkle representing the National Audubon Society.

You may proceed.

STATEMENT OF MAUREEN K. HINKLE, POLICY ANALYST, NATIONAL AUDUBON SOCIETY

Ms. HINKLE. Thank you, Mr. Chairman.

Out of compassion for the chairman and Mr. Fithian at this late hour—

Mr. BROWN. We know you are a woman of compassion, so we will insert your prepared statement.

Without objection, so ordered.

[The prepared statement of Ms. Hinkle appears at the conclusion of the hearing.]

Ms. HINKLE. I will dispense with reading it and I will touch only on those points that have not been previously dealt with today.

The National Audubon Society opposes all the major proposed amendments to FIFRA that are contained in H.R. 5203. We believe the only meaningful change proposed by H.R. 5203 that would benefit the public is the private right of action amending section 16(e).

The only other change we feel necessary at this time for these reauthorizing amendments is a provision for extension of the Scientific Advisory Panel with staggered terms for specified four panel members.

We are especially pleased to see section 16(e) of FIFRA which would provide for private right of action. Until the recent Supreme

Court rulings, the California Sierra Club issued and ordered April 28, 1981, we assumed, as others did, that private parties would have remedy for injury suffered for reason of a violation of FIFRA.

Without a specific provision, however, the Supreme Court has ruled that a private remedy is not implicit.

We, therefore, urge that this explicit provision be retained in the reauthorizing amendments.

We also favor that part of section 3 which would allow environmental groups to go directly to the Court of Appeals. We also support the provision for reentry standards to protect farmworkers and those living in and around pesticide treated areas.

Without provisions for adequate resources to enforce such regulations, and the priority deadline, we believe that these standards and buffer zones are likely to be delayed indefinitely.

I will be the only one here today to say that we oppose section 3 changes as embodied in H.R. 5203. Throughout these hearings you have expressed concern over the anticompetitive aspects of these amendments and of FIFRA generally. We share this concern.

Earlier it seemed that the amendments proposed for section 3 were arrived at unanimously by both large and small companies. Since that time it has come to our attention that not all of industry agrees that the compromise struck by this committee is desirable.

In addition, the Justice Department attorney, the one who litigated section 3(c)(1)(D) and section 10 cases successfully wrote a memoranda stating that the proposed amendments for these sections are unnecessary, anticompetitive, and prohibitively complex.

Should these objections not surface elsewhere at these hearings, we wish to call them to your attention. We have attached a letter from the chemical company which objects to any changes in section 3 and we have gone to lengths to quote from Pesticide and Toxic Chemical News' account of the memorandum written by the Justice Department attorney. We would also like to say that much has been talked about today and previously about commercial harm.

That requires a change in section 3(c)(1)(D).

In the opinion rendered by the EPA General Counsel on this issue in 1976 he stated that disclosure of test data will not cause substantial harm. In fact, he said the possibility that a firm would suffer substantial harm in this respect is so conjectural and remote that it is not a factor which should be allowed to override the public policy expressed in section 3(c)(2) favoring disclosure of test data.

It has been 6 years since that time and still industry can cite no specific case of commercial harm. Therefore, we believe section 3(c)(1)(D) does not need to be changed.

With regard to section 10, we have a few items that have not been gone into. EPA has yet to separate out bona fide trade secrets from disclosable health and safety data.

They have estimated that the scrubbing of this data—and this is on page 10 of my written testimony—is 45 years at a cost of \$5 million to \$10 million.

This would, in effect, mean that the system likely would remain on a request basis precisely because of a lack of resources.

We submit that serious public anxiety and suspicion regarding Federal registration decisions only hurts industry as well as EPA.

In many areas of the country, citizens literally do not want to be sprayed with any chemical. As long as information is not forthcoming, I predict this trend will grow.

We believe that the only way that citizens have any way of conducting or comparing some of the chemicals that people may choose to want to spray in their neighborhood is by information.

Therefore, we believe the only change that should be made in section 10 is to direct EPA to disclose health and safety information forthwith.

In regard to NACA's suggestion to remand section 10 to EPA for administrative solution, we believe that this study should not, if it is conducted, be open-ended. Otherwise, EPA can continue to deny requests telling us that we may not have this information pending completion of the study.

Knowing how complex this issue is for your members, we can imagine how EPA might decide that it is too complicated to resolve also.

In regard to the Scientific Advisory Panel, I would like to say I have attended at least 50 percent of the meetings of the Scientific Advisory Panel throughout its 5-year history.

H.R. 5203 merely extends the terms of the Scientific Advisory Panel. You, Mr. Fithian, were primarily responsible for mandating this Panel's existence in 1975. It has served your intent very well.

For 5 years the original Panel members served conscientiously and impartially and knowledgeably when they themselves did not know the information they eventually requested that specialist scientists who could be anticipated to be required for the particular chemical that they be brought into their deliberations so that they could give a more scientifically sound conclusion or decision on the compound.

The termination of the panel on September 30, occurred. It is overlooked by these hearings.

The new EPA Administrator dismissed all seven Panel members. I was told nothing could be done because it had already been done and from here on we will try to prevent politicization of the Panel by staggering terms.

But this already possibly has occurred, especially if you open up the nomination process to toxicology associations, one of which has joined the Council on Agricultural Science and Technology which is financed by industry.

And, as a result of this association members resigned because they said it was a political act. Yet, this is the organization that is now being looked to for nominations for the Scientific Advisory Panel which is supposed to be independent.

An entirely new panel will take time to get up to speed on the complex process. The review and analysis intended by this committee in establishing the Panel will take 1 year or so.

In the meantime, many of the decisions that EPA must make in this next year are political: 2,4,5-T, ferriamicide, toxaphene, ethylene dibromide, and 1080.

You must not let this Panel be politicized.

I wish to bring to your attention the fact that sometimes I get information directly from industry. The reason I do that is when

they find out that access is being denied to me, they think this is unfair.

So, they send me their studies themselves.

In conclusion, I would like to congratulate you for encouraging and speaking the breadth and depth of input for these hearings.

I regret that despite this input and a great deal of work on everyone's part that H.R. 5203 is too complex and confusing and unworkable.

So, therefore, except for sections 16(e) and 25(d) we urge a simple reauthorization of FIFRA.

Thank you.

Mr. BROWN. Thank you very much, Ms. Hinkle.

Mr. Fithian?

Mr. FITHIAN. Thank you, Mr. Chairman.

I have a comment. I want to thank Ms. Hinkle for this excellent testimony. I think some good material you have pulled together from some other sources are there, particularly the Department of Justice section. I find that very helpful to me.

Incidentally, we will be making some attempt at amendment on the Scientific Advisory Panel. Mr. Wampler will probably offer an amendment on that. We are working on that.

Mr. BROWN. I have no further questions.

Mr. Fithian?

Mr. FITHIAN. I have one further question.

We are at a remarkable point here today. This is the first time in 6 years that we have had unanimity on anything in this room. It does not seem like anybody wants to support section 10. [Laughter.]

If we leave out section 10 as proposed, which I think now is very likely to happen, do you expect to get at data that your group is interested in, but basically have been denied because of one court suit after another?

Do you expect to get at that fairly soon?

Ms. HINKLE. I have personal experience of a great variety which EPA can resort to in denying access to this information. I have standing several requests. One is for merely the application of ferriamicide. I just want the application from the State of Mississippi and not from the industry.

They will not give it to me until after their decision and if it is positive they will give me some scrubbed out material. If they deny it, of course, they will not.

But this is the compound that the organization that I was previously associated with had brought suit trying to enjoin a section 18 permit. It is a conditional registration this time.

But I am familiar with the compound. We call it "Son of Mirex." It is Mirex with a little ferris added to it. The State of Mississippi says it degrades into harmful substances. We have information that it degrades into kepone and photo-Mirex and photo-Mirex is several times more toxic than either Mirex or kepone.

So, we believe this is not an innocuous compound.

It is alleged to be cheaper than amdrow which has a conditional registration for both the aerial and ground application. So, the State of Mississippi would like this on the market. It would be so much cheaper.

EPA continues to deny a whole batch of information. In the case of amdraw they told me that the injunction would prevent any release. So, I said I wanted EPA's studies and USDA's studies. I did not want American Cyamid studies.

Again, I was told that they could not figure out which was which. So, I think I got one study in the end.

Mr. FITHIAN. I take it you think our efforts, however well intentioned or otherwise, to do something about section 10 would not help you out in your course of action; right? It would not help you in terms of getting information?

Ms. HINKLE. It is one thing to have legislation which bars it or makes it unduly complex which H.R. 5203 would and which was not clear before 1978.

But we prefer having the 1978 language because that at least sets the stage for our legal right to access to this information.

Now that the injunctions have been lifted in some cases, we will have to see what information is forthcoming.

I anticipate using this section, section 10, more now because the Agency will not even give me a copy of a speech. There is an iron curtain that has descended on EPA. They are paranoid about information getting out of the Agency.

But I do want section 10 language the way that the 1978 amendments have it.

Mr. FITHIAN. Thank you very much.

Thank you, Mr. Chairman.

Mr. BROWN. Thank you very much, Ms. Hinkle.

Our next witness will be Mr. Wally McGuire, director of government affairs of the California Governor's Office.

You may proceed.

STATEMENT OF WALTER McGUIRE, DIRECTOR, CALIFORNIA STATE OFFICE, ACCOMPANIED BY SUE MORELAND, CALIFORNIA STATE OFFICE

Mr. McGUIRE. Thank you, Mr. Chairman.

I thank you for once again listening to California on this important issue.

California views this as a Federal-State issue and one of health and welfare. I only bring that up because a number of the witnesses you have heard today and over the last year seem to agree with us on that.

These include a number of governors, directors of agriculture, and other groups from environmental groups and labor and civic and farm groups. To show how broad this coalition is, it includes EPA. We are seldom on the same side of an issue with them.

We are on the same side with them here.

I will move directly to two provisions and two parts of the testimony which I think will be helpful to the subcommittee.

First, this focuses on what the State of California has done in this past year to try to address some of the problems that have been raised in California and, of course, before this committee.

This morning as we for some time have heard a long list of horror stories about bureaucrats in California and how long it takes to put a pesticide on the market. I do not intend to go back

over some of the earlier testimony which said that there are an equal number of tragic stories on the other side. Sometimes we have a lot of pesticides to get onto the market with inadequate data or without taking enough time to see what the impact is.

But I point that out just to stress that California sees its obligation to protect the health and safety of the people in the State. We feel that section 24, particularly, which would be amended by the provisions of this bill, would hurt us in our ability to do that.

We are here today to discuss H.R. 5203 and its proposed changes to the Federal Insecticides, Fungicide and Rodenticide Act. Two sections of this bill concern the State of California—sections 5 and 11.

Section 5 proposes to change section 10 of the present law which concerns the definition of trade secrets and the procedure to be used in releasing to the public results of safety and health, and environmental effects studies conducted by companies and submitted to the Environmental Protection Agency in support of registration. The State of California supports the concept that people have a right to review health and safety data for chemicals used in their environment. For that reason, the State is concerned that section 5 of H.R. 5203 will restrict this important access to information. Congressional intent in the existing FIFRA law is that the public may review nontrade secret health and safety data. Yet, H.R. 5203 allows the Administrator of the Environmental Protection Agency to be the sole determinator of who may have access to this data. It does not provide for the judicial review of that decision and allows pesticide producers to testify against granting a citizen access to the reading room with no means of protest from the individual.

Section 11 of H.R. 5203 proposes to change section 24(a) of FIFRA. This portion of the bill was developed because the pesticide industry requested a fundamental change in the authority of States to regulate the sale and use of pesticides during hearings before this subcommittee last summer. California, in particular, would have been harmed by the industry's original proposed amendment. Since then, Mr. Chairman, you have been engaged in a long and complex process of problem identification, compromise, and dispute negotiations.

The amendment to section 24(a) of FIFRA contained in H.R. 5203 demonstrates how difficult such attempts to compromise become. Compromise on top of compromise on top of compromise has turned a simple four line section of the act into a complicated and burdensome section requiring 139 lines of procedural and administrative twists and turns.

Unfortunately, the result of such compromise as detailed in H.R. 5203, section 11, will create a Federal nightmare of redtape. This legislation is unnecessary. Existing avenues are available to the pesticide registrants to correct local procedural problems—these include administrative action, State legislation, and lawsuits. These approaches have not yet been exhausted.

There is no question, Mr. Chairman, we in California have had some pesticide company complaints regarding pesticide registration requirements. The amendment in H.R. 5203, however, does not address the real source of our problems. Allow me to explain.

The California Pesticide Registration Regulations are presently being amended in several sections of our statutes to provide relief in areas that have been recognized as burdensome in the registration process and subsequent use of the product. These areas include relief from certain data requirements and modification of public noticing requirements prior to use of the pesticide.

There are four things that the State of California has recently done which I think address and take care of, to a large extent, the problems that have faced the manufacturers and the people who use pesticides in the State of California.

The first one, by the way, deals with the State of California accepting data from other sources, particularly other States.

For example, sections 2372 and 2373 are being amended to eliminate the need for registrants to develop certain kinds of data in California.

This change allows data developed under similar environment conditions outside California to be evaluated in support of California registrations. It especially eliminates unneeded duplication and provides registrants with more flexibility and use of data.

This applies to the efficacy and residue areas where prior to this amendment the State of California demanded that those tests be done in California.

They are now willing to accept test results as long as there are similar conditions from other States and other test results.

The second area is that of emergency use of pesticides. Section 2443 presently requires that proposed decisions relating to registration shall be posted for 45 days for public review and comment.

This requirement has, on occasion, interfered with the urgent need to mitigate a pest problem by way of limiting California's authority to register a new use of a federally registered pesticide on a timely basis under provisions of section 24(c).

Section 2443 is also being amended to allow use of a pesticide proposed for registration prior to the end of the 45-day public comment period where the need is justifiable.

This is not to say that we will not continue to post the new use for 45 days, but we will allow the interim use of it in an urgent situation.

California recognized that the Environmental Protection Agency could register pesticides citing data owned by other registrants and, at the same time, enable compensation for the owner.

California was provided the mechanism in California Administrative Code, Section 2369(d), to parallel a part of the EPA process and allow use of data, the part which we were not given, which was the compensation part, feeling that that was taken care of at EPA.

This would allow use of data submitted to the California Department of Food and Drug Culture for applicants who wish to cite data on file in California.

Section 2369(d) reads, in part:

... when data is required by this article (Article 5) or Article 4, the registrant may, in lieu of submitting such data, reference appropriate data previously submitted for the same pesticide.

California was immediately enjoined by the National Agricultural Chemical Association—*NACA v. Rominger*—contending that such referencing is an unlawful taking of property.

The affidavit of Daniel M. Dooley, the Chief Deputy Director of the Department of Food and Agriculture at that time, submitted to the U.S. District Court for the Eastern United States, affirmed Section 2369(d) authority.

That affidavit states, in part:

When a registrant requests California registration based upon data supplied by another registrant, the Department will assure that the Environmental Protection Agency has registered the product of the second applicant.

The Department accepts the propriety of EPA's action with respect to protection of data submitted by the first registrant and will permit registration of the additional product in California without requiring that the first registrant give approval in addition to that necessary for the later registrant to obtain FIFRA registration.

It further states:

When a California registrant submits data to the Department in addition to that provided to EPA, the registrant may submit the data marked "confidential" or otherwise indicate it is entitled to trade secret protection.

If a later applicant requests California registration first registrant notifies the Department that it has no objection to the use of the data to support the second application.

The litigation of *NACA v. Rominger* prohibited the referencing of data and California's attempt to provide a parallel system of registration.

This action required California to have in possession a letter of authorization from the owner of the data to be cited that would allow its use.

This quickly became the principal objection of CSMA to the California registration process.

This dilemma presented three problems:

One, chemical companies could not always obtain a letter of authorization from the owner of the data:

Second, many of the pesticides were registered in California by the owner of the data prior to the 1980 data requirements.

The present regulations required that a summary of the data required by 40 CFR, subchapter E be submitted to support registration.

And, three, in many cases, even though the applicant was able to obtain an authorization to use data, neither the applicant nor the primary registrant could comply with the data requirements of 40 CFR, subchapter E.

California has proposed, and it was recently accepted, that an amendment would take care of the problem which is a substantial change from previous practice in California. Namely, they have amended section 2360(a) to provide discretion in requiring summaries of all the federally required data.

California will still be limited in its authority to register pesticides without authorization from the primary registrant where the applicant cannot provide data to support their application.

Since other States are not enjoined by *NACA*, they do not experience the same difficulty in accepting the EPA cite-all registrations.

Section 2369(d), California Administrative Code, is amended to reflect the propriety rights for data and requires authorization for its use by another registrant.

That was imposed on us by a lawsuit.

The fourth change that we have made in California is the conditional registration requirements. In addition, California conditional

registration requirements are being amended to provide for the difference in minimum data requirements needed for products containing active ingredients not previously registered as opposed to products containing active ingredients presently registered.

The present section sets standards for minimum data that must be provided before conditional registrations will be granted.

The new section establishes different standards for products containing previously registered active ingredients as opposed to products containing new active ingredients not previously registered, with more restrictive standards for the latter.

This change will make the registration process more responsive to companies who do not have data, or who cannot obtain authorization to reference data.

The change will also be of special benefit to speciality manufacturers who deal mostly in products that contain formulations of active ingredients presently registered.

The combination of the changes in this section complimented with the changes in section 2360(a) will provide a reasonable and much more flexible mechanism for registration of these products.

That is a summary, really, of the steps that California has recently taken. I think you will see they are substantial and I think they go a long way in meeting some of the objections.

If not, the majority of objections have been raised recently. We feel we have been able to do that in a way that is consistent with the State's ability to protect the health and safety of our citizens.

We also think that the changes are happening at the appropriate level of government. They are happening at the State level and there is a process for doing it and in fact there is an on-going process in California right now, the AB-1111 process where regulations are reviewed to see if there is not some way to streamline them and make sure that there is not unnecessary redtape.

The majority of the responsible corporations in the pesticide industry accept the validity and usefulness of the data requested by California. Most companies holding registrations have either already complied with California's data requirements or have begun the tests needed to generate additional data required by California and not otherwise available. With these changes in the California Department of Food and Agriculture's program in place, which we have already outlined, the majority of the problems industry has presented to you will be solved—and at the local level where such fine-tuning should occur.

Keeping in mind that the California Department of Food and Agriculture considers industry's problems to be in the process of correction by State administrative and legislative procedures, the State of California would like to state its position once more: We are opposed to any change in section 24(a). California has repeatedly stated its position and that position is a part of the official records of the hearing file pertaining to proposed changes in section 24(a). The director of the California Department of Food and Agriculture, Mr. Richard Rominger, appeared before the House Agriculture Subcommittee on Department Operations, Research and Foreign Agriculture in June 1981 and expressed California's opposition to any changes in section 24(a) of FIFRA. Mr. Rominger appeared again before the subcommittee on September 4, 1981 in Sacramen-

to, Calif., and reaffirmed that opposition. He also stated the position again in a letter, dated November 5, 1981, to the Honorable George E. Brown, Jr. The State's position has not changed; and once again, California reaffirms its opposition to any change to section 24(a).

H.R. 5203, with its proposed amendments to section 24(a), if implemented, will effectively eliminate a State's ability to assess the health hazards of pesticides or the potential for adverse environmental effects. To subject California's 24 million plus people to the exposure of over 500 million pounds of pesticides each year without the ability of State government to assess the hazards is unreasonable, inappropriate, and clearly an attack on the State's rights to protect its citizens.

Mr. Chairman, let me point out some of the substantive problems with H.R. 5203, problems which we firmly believe will cripple our Department's ability to proceed with its current pesticide registration program.

On page 49 of H.R. 5203, line 13, a State is given the option to request data from an applicant, or if the applicant refuses or is unable to cooperate, from the Administrator from EPA.

I assure you many companies will avail themselves of this option and force CDFA to obtain the data from EPA.

Yet, line 18 states that the Administrator of EPA shall make the data available "subject to the provisions of section 10."

That means that California would be denied access to three types of information now defined as trade secrets in section 10—manufacturing or quality control processes; vital information on the composition and methods to test for inert ingredients added to pesticide products; and the quantities and identities of deliberately added inert ingredients.

Our earlier testimony documented a number of cases where the deliberately added inert ingredients in a pesticide produce were the cause of a health problem for many California fieldworkers.

The proposed amendments will make it impossible for California to obtain data necessary to assess the hazards of pesticides.

They will force California to either deny applications or to register pesticides without assessing the hazards and waiting until the effects of their use are apparent in poisoning incidents or environmental contaminations.

Another feature in H.R. 5203 supported by industry is the new authority of the Administrator of EPA to review a State's request.

The Administrator is granted the authority and responsibility under certain circumstances to overrule or modify a State's data request.

Please allow us to state clearly for the record, once again, what this means to California. California law explicitly requires the State to reach regulatory decisions after a careful review and balancing of the scientific data relating to a pesticide's properties and toxicity.

An abridgment of the State's ability to obtain complete pesticide data is therefore de facto preemption of the State's right to make its own regulatory determination.

Industry's contention that H.R. 5203 does not preempt States rights is like saying that a schoolteacher can perform his or her

educational duties without books, or that a judge can reach a fair decision in a case without a chance to review the facts.

The protection afforded industry by the administration's right to review State data requests is unnecessary. Applicants for registration who can show convincingly that a State data request is "arbitrary and capricious" have many other avenues of judicial, administrative, and legislative relief, all of which should be exhausted before Congress should even be asked to intervene.

Industry has exhausted none of these avenues in California, nor have they been able, or even tried, to demonstrate that a specific California data request is "arbitrary and capricious."

The proposed amendments are generally unclear and subject to a broad latitude of interpretation. They will also create an additional expense to registrants.

California requires an application fee to be submitted with the product registration request.

Section (3)(a)(1) suggests a denial of the application may be the only way to prevent registration if data are not submitted with the application.

Data requests referred to the Administrator have 60 days for a response. Denial of these applications and subsequent resubmission would require another fee.

The California pesticide program is an integral part of the State's responsibility to promote and protect agriculture. It also must remain accountable under State government mandates to protect the health and welfare of the citizens of the State.

The proposed amendments to section 24(a) effectively eliminate both of these responsibilities and leave the protection of citizens and environment in the hands of chemical companies whose primary motivation is to market pesticides.

The long-term effect of such action will result in increased environmental contamination and a significant increase in pesticide exposure incidents by those who mix, load, apply, use, and work around pesticides.

Without access to such trade secret information as analytical test methods in which to identify pesticide residues in soil, on plants and food, the citizens of California and our State's environment will be placed in a very vulnerable and unprotectable position.

California urges you to carefully consider the impact of these proposed amendments, as well as the consequences, and not give in to the pressures of those whose primary motivation for their adoption is sale of pesticides in contrast to those in opposition to their adoption who propose to gain knowledge of their hazards and provide the means to promote their use in a safe and effective manner.

Thank you, Mr. Chairman.

Mr. BROWN. Thank you.

Mr. Fithian?

Mr. FITHIAN. Thank you, Mr. Chairman.

Mr. McGuire, I want to thank you for your articulate statement and for bringing us up to date on the changes that have taken place in your law.

Let me first note the absence in your testimony of what can be recognition of the fact that the proposed section 24 change deals

with nonagricultural rather than agricultural products so that, for example, the statement on page 12 you say:

"The California pesticide program is an integral part of the State's responsibility to promote and protect agriculture."

It leads me to believe, Mr. Chairman, that we have these two ships, adversaries if you will, passing in the night and neither paying much attention to what the other one has said, if paying any attention at all.

Mr. McGUIRE. We are as concerned about the nonagricultural uses. That is a misstatement in my statement. In fact, the majority of the recorded poisonings or mishaps are in that area.

Mr. FITHIAN. What is that?

Mr. McGUIRE. The testimony is meant to cover both. That is an omission in the drafting of the statement. We are as concerned about these problems and the fears about the regulation of nonagricultural pesticides.

Mr. FITHIAN. Did you talk about the relative incidence?

Mr. McGUIRE. That is right. I am told by our department of agriculture that there are greater number of incidents of poisonings in the nonagricultural area, although the severe ones are in the agricultural area.

Mr. FITHIAN. There has been a lot of discussion on whether or not the State is requiring more data than it needs and earlier California testified that additional data requests were taking place in 10 or 15 percent of the requests. Later that went up after review in California at the committee's request to 85 percent. That is, 85 percent of the applicants were requesting additional data.

I do not know whether that constitutes arbitrary and capricious in line with your testimony on page 11. But it certainly must make you aware of why the weight of inconsideration—I should say unconcern on the part—and others have come to focus on this, and it has become pretty much a routine thing and there is a regular request for additional data.

Mr. McGUIRE. I think those figures were arrived at prior to the measures that I mentioned. Hopefully, the steps that California has taken will reduce that.

Ms. MORELAND. I work for the State of California also.

One of the questions Mr. Fithian had about the additional data that California requests has to do with the direction of California's program. We in California are concerned and have a complementary approach to EPA.

We are concerned about the users and the types of exposures among the people who make pesticides. The user approach is concerned with poisons that are the result of skin absorptions. EPA, at this point, does not request skin absorption data; although the EPA's Scientific Advisory Panel has advised EPA that they should start this type of data request.

So, there are some additional bits of information that the EPA has agreed with us should be supplied.

That was in the testimony that we presented on September 4, 1981, from Peter Kertz, one of our toxicologists.

Mr. FITHIAN. Let me go back to the earlier question, that is, the comment earlier that you made that you are having as many or more problems with nonagricultural use materials as with agricul-

tural use materials. Pounds, or whatever it is that you use out there, are agricultural rather than nonagricultural?

Mr. McGUIRE. If you are judging it from poundage of pesticide use, agricultural use is overwhelming.

Mr. FITHIAN. But your earlier statement lead me to think that you were more concerned about nonagricultural, or were nonagricultural and agricultural equal?

Mr. McGUIRE. No, I am equally concerned. I thought you were indicating that we were only concerned about agriculture. I wanted to say that we are equally concerned with both.

Mr. FITHIAN. The problem we have gotten into is this. I do not know whether complaints are right or not. But the complaints continue and have for a year or more that there seems to be little distinction.

Maybe the changes in the law will help. I think it is fair to say that your characterization of that as progress and change and trying to accommodate is an accurate one.

It seems, as you describe the laws there that these are steps forward to accommodation. But there has been an awful lot of complaint that this kind of an across-the-board approach causes you to apply the same kind of structures whether it is extending the length of a dog collar or an additional bowl cleaner. I think that was Dr. Engel's comment this morning; or, are you getting into a serious matter.

It must be apparent that when you are dealing with a relatively minor use—and I do not like the term “minor use” because of the legal termination—but compared with the use out with the fieldworkers that the weight of providing a second round of data and so on becomes much heavier on someone who has a relatively small market than if you were dealing, let us say, with the entire tomato crop or the entire wheat crop, or whatever it is, in California.

Do you see in your administrative procedures taking into consideration that when you ask for additional data?

Mr. McGUIRE. I think, in fact, that is the very point that is reflected in these changes that have been suggested and hopefully will be placed into effect in California.

Many of those requests came on the me-too registration. When you look at the lawsuit, the Rominger lawsuit, we were required to make the data request. We could not rely on previous information that might be in our files.

Of course, section 10 prohibits us from going to EPA unless we want to license these without data.

Mr. FITHIAN. So changes in your law will accommodate that?

Mr. McGUIRE. Yes, I am saying that. What happens now is that the States have been given the power in their discretion to either make a data request or not. I think they would plan to make those requests only when there is a major new use or a severe data gap or there is some reason to believe that they need the extra data.

Mr. FITHIAN. I have one more question. This pertains to testimony on page 9.

I am struck by the argument. I want to call attention to this. At the bottom of page 9 you say:

Gentlemen, I assure you, many companies will avail themselves of this option and force CDFA to obtain the data from EPA. Yet line 18 states that the Administrator of EPA shall make the data available "subject to the provisions of section 10."

This calls into question two things. One, the reasoning behind this. I am not quarreling with it, but I am trying to get at what you are talking about.

Is it your belief that the respondent would say go get it from EPA on the grounds of trying to save money? Also, if we threw out section 10 changes which seem imminent, are you now referring to section 10 as we are proposing to change it or the old section 10 as the law now stands?

Mr. McGUIRE. I believe to both.

Ms. MORELAND. It is both old and new.

The disclosure section is in both of them. They have not been changed.

Mr. FITHIAN. Even if we chuck out everything we have done with section 10?

Ms. MORELAND. We will still be deprived of trade secret information.

Mr. FITHIAN. Your statement would remain operative?

Ms. MORELAND. That is true.

Mr. McGUIRE. Yes; if section 24 goes into effect, that would affect it.

Mr. FITHIAN. What about the background to your assertion that you expect the companies to go get it from EPA?

Mr. McGUIRE. Basically that is a judgment subject to one's view. It is based on the difficulty we have had. In certain cases we have gotten data on the number of requests made.

Mr. FITHIAN. Would your operation be impaired if you had to get it from EPA?

Mr. McGUIRE. Yes, if we had to go to EPA and—it restricts the amount of information you could get and the content.

In section 10, whether or not you amend it, it is proposed here.

Mr. FITHIAN. You are saying that the companies would direct you to EPA not as an economic measure that we will not get all the data prepared—

Mr. McGUIRE. No, I was not trying to say they were doing it in order to hide or not give data. It is just based on the idea that it would be much easier than to provide the data themselves. That is the primary complaint.

Mr. FITHIAN. My question was not clear.

Are you saying they would utilize the escape into the "Go get it from EPA" syndrome because they did not want you to have the data in your restriction under section 10 of the kinds of data you can get readily from EPA?

Or, do you foresee them doing this as an economic or convenience matter?

Mr. McGUIRE. I do not ascribe motives. I do not say they do not want to avail themselves of section 10. I do not want to say they want to do it for that reason.

But if section 24 passes as you have discussed it here in H.R. 5203, that is a possibility. That is the prohibition that we would have in getting data.

Whether they would do it for that reason or not, I do not know. I would not go on record for that.

Mr. FITHIAN. Thank you.

Our distinguished Californian here, the chairman, has been exceedingly generous to me. I thank him. Mr. McGuire, our staff has labored long and arduously to draft the language which has been voluminously criticized this afternoon and this morning. It is enough to make them truly humble. [Laughter.]

Mr. BROWN. The language in section 24 that you referred to provides for review by EPA over certain data requests. However, EPA would reject a data request only on the grounds that it is arbitrary and capricious. California would never submit requests that were arbitrary and capricious, would it?

Mr. MCGUIRE. Of course not.

Mr. BROWN. In which case EPA would never have any reason to reject any of these requests; would they?

Mr. MCGUIRE. They certainly have. The chemical companies currently have the right to object in courts if they feel their actions are arbitrary and capricious.

So, I guess this would be unnecessary.

A lot of the criticism that has been directed to the State of California assumes basically there has been arbitrary and capricious actions on the part of State bureaucracy and that they have made a request which is not necessary.

So, what we have is legislation which basically says to move it out of there and put it in the hands of the Administrator of EPA.

I am saying that maybe there is no solution. How do we have a protection against arbitrary and capricious actions of the Administrator of EPA in denying us access to information?

Mr. BROWN. That is a good question. I am not at all sure I know the answer.

Ms. Moreland?

Ms. MORELAND. Mr. Fithian brought this up earlier about putting more things into courts than we probably need to have in courts. We already have one level of objection open to the industries within the current section 24(a).

If we amend it as you have in H.R. 5203 we will have the additional level of the EPA acting as a mediator.

Since California, if we can follow your reasoning, would never make arbitrary and capricious requests, California would feel very strongly if the EPA denies its request. Then you end up with California suing EPA and tax money pays on both sides. It drains time off EPA's limited money and budget.

Then you end up, if it is decided yes, that California was right after all, that the companies sues the State anyway.

H.R. 5203 creates one more level of judicial review.

Mr. BROWN. This country has had a genius of providing checks and balances since the founding of the country and the writing of the Constitution.

I am sure that no one would ever contend that the House is arbitrary and capricious just because the Senate is there to cool the passions of the House or that we need the President to veto legislation that is arbitrary and capricious even though both the House and Senate agree.

So, the principle here is that no human action is completely infallible and sometimes a balance is satisfactory.

You have testified at considerable length to the changes that California has made in the regulations. I presume this indicated that prior to the changes they were less than perfect; right?

Mr. McGUIRE. I was not involved in that, but I would acknowledge there were some problems. They have addressed them. I think that is the forum to do it.

Mr. BROWN. Now that the changes have been made, everything is perfect?

Mr. McGUIRE. No, there is an ongoing process that exists in California. I do not think anything is ever going to be perfect.

Mr. BROWN. We agree with you on that.

I am not trying to belittle the great State of California, of course, inasmuch as I come from that State.

Let me ask you with regard to your objections to section 24 based upon the issue of State's rights. Are you a recent conversion to that doctrine?

Mr. McGUIRE. I think the State has been pretty consistent in their rejection of any change in section 24(a).

Mr. BROWN. On the basis of States rights?

Mr. McGUIRE. They may have listed other reasons but that is my understanding that they believe in the States' police power and their objections to protect their citizens in this area.

Mr. BROWN. Is that an immutable principle?

Mr. McGUIRE. No; I think you would find the State all in favor of an EPA and a strong EPA. It is not that the State has the sole right, but rather than the original intent of FIFRA sets the minimal standards and allows the States, particularly where they think they have some special need to establish stronger measures, to do so.

Mr. BROWN. We went through this debate at considerable length in prior generations over the questions like voter qualifications, for example, in which the Federal Government sets the minimum requirements of the Constitution or the Constitution does, and some of the States say they could do a better job by imposing a requirement to understand the Constitution or something like that.

Do you subscribe to that doctrine of States rights?

Mr. McGUIRE. No, I do not.

Mr. BROWN. So there are exceptions to the principle?

Mr. McGUIRE. Certainly. That is why I think the State believes the Federal Government has a minimal safety standards role to play all across the country.

I do not think that the State at this point feels that EPA particularly with the budget cuts is going to be able to provide the measure of support that is recommended in H.R. 5203, with the primacy of the regulations shifting to the Federal level.

Mr. BROWN. Well, I find myself in an odd position here seeking to advance some of the arguments in support of the language of the bill, but I think some of the objections to it have been carried a little further than the facts might actually warrant.

I would like to have a balanced reflection in the record on that.

I have no further questions. So, we thank you both for your excellent testimony.

Our last witness this afternoon, who must be commended for his patience, is Theodore Reuter who is director of the Reuter Laboratories in Haymarket, Va.

We thank you for your patience, Mr. Reuter, for remaining with us.

You may proceed.

**STATEMENT OF THEODORE E. REUTER, DIRECTOR, REUTER
LABORATORIES, INC.**

Mr. REUTER. Thank you, Mr. Chairman.

Mr. Chairman and members of the subcommittee, it is a pleasure to be here today.

As director of one of the largest producers of biological insect controls, my testimony addresses a number of problem areas concerning EPA regulations as they were formed from the United States Codes, and the inability of the regulations to adequately serve the EPA, industry, and the American public in particular regard to pesticide registrations.

Primarily, I wish to focus on the specific language of section 3(c)(1)(D) of FIFRA, as amended.

The EPA regulations currently in force and as currently interpreted by EPA counsel, fail to properly follow the United States Codes which clearly state an applicant for an EPA pesticide registration may either cite all (CFR 40, P162.9-4(b)) or submit data pertinent to the application (CFR 40, P162.9-8).

In the Code of Federal Regulations title 40, P162.9-8 is titled "Alternative Procedure for Certain Applicants for Conditional Registration."

Quote from it.

(a) An applicant for conditional registration of a new product (or for conditional amendment of an existing registration) need not comply with PP162.9-4 and 162.9-5 if: (1) Each of the product's active ingredients is contained in some product currently registered under FIFRA; (2) The product will be labeled as an end-use product, as defined in P162.9-7(c); and (3) The applicant complies with paragraphs (b) through (f) of this section. The requirements that are made are tests of the finished product for safety, and appropriate offers to pay compensation if applicable. (See CFR PP162.7, 162.8 and 162.9 attached).

The EPA policy, however, in reference to (1) above, states that the product's active ingredients must be purchased from a manufacturer who has the ingredient registered as a pesticide.

Thus, EPA has made an illegal interpretation of the code either purposely or inadvertently. Despite the exact stipulations of the code, the EPA has set aside the use of the alternate form of registration, and requires all applicants to comply with the cite-all form of registration.

The requirement has placed many industrial firms in the position of being unable to obtain registration because cite-all is required but another part of the code permits a 10-year exclusive use of data by the company submitting it.

Thus, the registration process is halted and cannot proceed to completion because the applicant must cite-all, but cannot cite-all.

It is this untenable and unjust situation that has led to the presentation of the statement.

To simply state the situation, Reuter Laboratories was told by EPA that they would not allow us to submit our own data in this situation, and advised that if EPA were to grant us a registration, they would be sued by the firm holding the original registration.

The insect involved is not native to the United States and causes millions of dollars of damage to trees, lawns, ornamentals, and crops each year.

Several million in tax dollars were spent by USDA scientists to isolate and synthesize a certain insect sex attractant, called a pheromone. Years of work went into this product, with scientists processing 17 tons of insects to obtain just 1 gram of natural pheromone for analysis.

To quote leading experts in the pheromone field: "No commercial company could have been able to afford the amount of research necessary to accomplish this important breakthrough."

Pheromones reproduce an insect's natural sex scent, attracting male insects into mechanical traps from which they cannot escape. Pheromones and other biological controls are vital to America's future agricultural economy for a variety of reasons.

In the first place, many insect pests are becoming immune to chemical pesticides, requiring the use of heavier and heavier dosages on agricultural crops. Certain new resistant strains cannot be controlled at all.

Second, chemical pesticides contaminate the environment and their use must be carefully controlled for food crops.

Third, many chemical insecticides are made from oil derivatives so that their manufacture helps deplete our petroleum reserves and forces higher prices upon the consumer for many oil products.

Finally, the American Cancer Society reports a higher incidence of cancer among farmers than city dwellers. Many medical doctors believe there is a direct link to the farm usage of huge amounts of chemical pesticides and fertilizers.

This EPA stand is particularly insulting to Reuter Laboratories because:

One, the product involved is not a pesticide, but an insect attractant, and,

Two, the product is public patent held by the U.S. Department of Agriculture which has granted Reuter Laboratories a nonexclusive license to manufacture this item.

In fact, USDA officials charge that EPA has usurped the patent laws and has given a monopoly to a single party other than the inventor. Such action, USDA says "is against the Federal Law."

Furthermore, Public Law 96-517 of December 12, 1980, signed by President Reagan shortly after taking office, states that no Federal agency shall grant exclusive license of a federally owned invention, if such action lessens competition in any line of commerce to which the technology of the invention relates.

I have attached a copy of United States Code 209 94 Stat. 3024 which I would like placed in the record.

Mr. BROWN. Without objection, so ordered.

[The attachments to the statement are held in the subcommittee file.]

Mr. REUTER. Aside from the illegality of the EPA action, or inaction, is this matter of the restraint of trade resulting from one com-

pany being given exclusive EPA permission to market its product, placing an unnecessary and unfair disadvantage upon the consumer in terms of higher prices and lack of product availability.

This simply means a company obtaining an EPA "exclusive" registration can charge whatever he wants for his product and take his time about delivering it.

In the Reuter case, the availability of the product made possible by more than one supplier is crucial, even critical, toward alleviating and helping control a specific insect problem area.

On the other hand, biological insect controls are safe for use within the environment. They are hosts specific, eliminating the target insect pests while leaving the other insects, animals, and man unaffected.

Many are longlasting controls providing the best protection at the lowest cost.

The EPA was originally formed to help protect the environment, and to seek alternatives to the use of chemical pesticides. Its integrated pest management, called IPM, is dedicated to exploring and proposing insect controls, combining a variety of measures and resources, including biologicals.

Yet, despite this dedication to environmental safety, the EPA has continued to deny Reuter a registration for an important biological product for almost 2 years, even though our firm has the ability to produce this important product and to provide the EPA with required registration data.

It is critical for our firm that we enter the competitive open marketplace, now. If a delay of a third year is allowed, the target insect will become a worse problem.

We, therefore, formally ask that this committee immediately consider and recommend the amendment before you to correct the cite-all situation now.

This important amendment must not be delayed because of the inability to resolve section 24. To do so will have catastrophic effects on Reuter Laboratories and industry as a whole.

Our argument is also served here through the intent of the U.S. trade laws which protect and preserve free trade and guard against unfair competition.

In summation, the EPA must be directed to encourage rather than discourage registrants of biological control agents; to accept every applicant's data so that the EPA's pesticide information base will be broadened; and refrain from ever again giving a monopolistic advantage to any one firm that would cause restraints of trade, high prices and limited product availability—especially in the area of U.S. public patents.

To allow the present dilemma to continue, even for the shortest time, can only breed possible misuse and continued confusion within the Agency.

We also submit to you, at this time, our own version of part of the language of the new amendment, and ask that the subcommittee act forthwith.

I would ask that this be placed in the record at this time.

Mr. BROWN. Without objection, so ordered.

[Proposed language follows:]

Section 3 (C) (1) (D)

(D) The data required for registration. An applicant may satisfy this requirement by any of the following procedures or any combination of these, except to the extent that the applicant is precluded from relying on data by the provisions of subparagraphs (i) through (iv).

Procedure A. Submission of data which have not been submitted previously.

Procedure B. Citation of data previously submitted to the Administrator.

Procedure C. Citation of data which does not have as its source the original data submitter, an applicant for an experimental use permit, an applicant for an amended registration, or by an applicant for re-registration, in which case subparagraph (vi) shall apply.

Procedure D. Submission of entire data requirements for the active ingredient of the applicant's product.

(vi) When an applicant is precluded from relying on data by any of the provisions of subparagraphs (D) (i) through (D) (iv), the applicant shall support his applications for registration, experimental use permit, amended registration, or reregistration by submitting data on the active ingredient (s) or pesticide product, or both, which data shall be all of the following:

1. The same tests and test results which were required by the Administrator, of the original data submitter.
2. The same tests and test results which were required of an applicant for an experimental use permit, an amended registration, or reregistration by the Administrator.
3. Additional new data on the active ingredient or pesticide product which the Administrator may require.

(d) The provisions given in the paragraph (C) (1) (D) shall apply to applications for registration which have been submitted after September 30, 1978.

Mr. REUTER. This concludes our formal presentation. Thank you.

Mr. BROWN. Thank you very much for bringing this matter to our attention.

Mr. FITHIAN. Thank you, Mr. Chairman.

Let me join the gentleman in thanking him for coming. Some of us have long had the notion that one way or the other our regulatory arms are creating consolidation in industry that is harmful. This is clearly a documented case.

Mr. BROWN. I assure you that the subcommittee will expeditiously move forward some language to change the cite-all provision.

But in the meantime I will direct the staff to inquire of EPA the details of your situation and see if there is not an administrative remedy that might be quicker.

I do not know that there is, but we will indicate our concern over this matter.

Mr. REUTER. Thank you.

Mr. BROWN. We want to thank you for your testimony.

With that, the subcommittee will stand adjourned.

[Whereupon, at 5:30 p.m., the subcommittee was adjourned.]

[The bill H.R. 5203, prepared statements of witnesses, and submitted material follow:]

97TH CONGRESS
1ST SESSION

H. R. 5203

To amend the Federal Insecticide, Fungicide, and Rodenticide Act.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 14, 1981

Mr. BROWN of California (for himself, Mr. WAMPLER, Mr. BOWEN, Mr. EMERSON, Mr. EVANS of Iowa, Mr. FITHIAN, Mr. ROBERTS of Kansas, and Mr. THOMAS) introduced the following bill; which was referred to the Committee on Agriculture

A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Federal Insecticide, Fun-
4 gicide, and Rodenticide Act Amendments of 1981".

5 DEFINITIONS

6 SEC. 2. Section 2 of the Federal Insecticide, Fungicide,
7 and Rodenticide Act is amended by—

8 (1) amending subsection (ee) by striking out "or"
9 immediately before clause (4) and inserting before the

1 colon at the end of clause (4) the following: “, or (5)
2 using a registered pesticide for the formulation of an
3 end-use product or repackaging a pesticide which is an
4 end-use product, unless such use is prohibited by the
5 labeling”;

6 (2) adding at the end thereof the following new
7 subsections:

8 “(ff) NEW ACTIVE INGREDIENTS.—The term ‘new
9 active ingredient’ means an active ingredient that has not
10 been listed as an active ingredient in the ingredient statement
11 of any registered pesticide product that has been registered
12 under this Act.

13 “(gg) NEW USE.—The term ‘new use’ means—

14 “(1) a change in the use pattern of a pesticide
15 from nonfood to food use, food to nonfood use, outdoor
16 to indoor use, indoor to outdoor use, terrestrial to
17 aquatic use, aquatic to terrestrial use, nondomestic to
18 domestic use, domestic to nondomestic use.”.

19 **REGISTRATION OF PESTICIDES**

20 **SEC. 3.** Section 3 of the Federal Insecticide, Fungicide,
21 and Rodenticide Act is amended by—

22 (1) amending subsection (c)(1) to read as follows:

23 “(c) **PROCEDURE FOR REGISTRATION.**—

1 “(1) STATEMENT REQUIRED.—Each applicant for
2 registration shall file with the Administrator a state-
3 ment which includes—

4 “(A) the name and address of the applicant
5 and of any other person whose name will appear
6 on the labeling;

7 “(B) the name of the pesticide;

8 “(C) a complete copy of the labeling of the
9 pesticide, a statement of all claims to be made for
10 it, and any directions for its use;

11 “(D) data as required for registration as pro-
12 vided in subsection (h) of this section with the
13 trade secret or commercial or financial informa-
14 tion marked as required by section 10(a) of this
15 Act;

16 “(E) the complete formula of the pesticide;
17 and

18 “(F) a request that the pesticide be classified
19 for general use, for restricted use, or for both.”;

20 (2) amending subsection (c)(2)(A) to read as fol-
21 lows:

22 “(2)(A) DATA IN SUPPORT OF REGISTRATION.—
23 The Administrator shall publish guidelines specifying
24 the kinds of information which would usually be re-
25 quired to support the registration of a pesticide and

1 shall revise such guidelines from time to time. If there-
2 after the Administrator requires any additional kind of
3 information under subparagraph (B) of this paragraph,
4 the Administrator shall permit sufficient time for appli-
5 cants to obtain such additional information. The Ad-
6 ministrator, in establishing guidelines for data require-
7 ments for the registration of pesticides with respect to
8 minor uses, and with respect to various types and
9 classes of pesticides, shall make such guidelines com-
10 mensurate with the anticipated extent of use, pattern
11 of use, and the level and degree of potential exposure
12 of man and the environment to the pesticide. In the
13 development of these guidelines, the Administrator
14 shall consider the economic factors of potential national
15 volume of use, extent of distribution, and the impact of
16 the cost of meeting the guidelines on the incentives for
17 any potential registrant to undertake the development
18 of the required data. Guidelines and modifications
19 thereof shall be published in the Federal Register. The
20 Administrator shall provide for public comment for
21 Agency guidance in development of such guidelines or
22 modifications. Except as provided by section 10, of this
23 Act, within 30 days after the Administrator registers a
24 pesticide under this Act the Administrator shall make
25 available to the public the data called for in the regis-

1 tration statement together with such other scientific in-
2 formation as he deems relevant to his decision.”;

3 (3) amending subsection (c)(2)(B) to read as fol-
4 lows:

5 “(B) ADDITIONAL DATA TO SUPPORT EXISTING
6 REGISTRATION.—

7 “(i) If the Administrator determines that ad-
8 ditional data are required to maintain in effect an
9 existing registration of a pesticide, the Adminis-
10 trator shall notify all existing registrants of the
11 pesticide to which the determination relates and
12 provide a list of such registrants to any interested
13 person.

14 “(ii) Each registrant of such pesticide shall
15 provide evidence within 180 days after receipt of
16 the notification specified in clause (i) of this sub-
17 paragraph that it is taking the appropriate steps
18 prescribed by the Administrator to secure the re-
19 quired data. Such steps shall include entering into
20 a joint data development arrangement, unless
21 such registrants unanimously agree otherwise, or
22 unless the registrant qualifies for an exemption
23 under subparagraph (D) of this paragraph. As an
24 initial cost of participation the joint data develop-
25 ers shall divide equally 25 percent of the estimat-

1 ed total cost of producing the required data or
2 each shall pay \$100,000, whichever is less. The
3 balance of the cost of producing the data shall be
4 paid by the joint data developers as needed, and
5 shall be shared by each joint data developer on
6 the basis of its United States market participation
7 for the pesticide being tested, based on total
8 pounds sold or used annually. Each joint data de-
9 veloper's market participation shall be adjusted
10 during the period of the data development so that
11 the most recent sales figures are used to compute
12 each member's market share for the purpose of
13 determining its share of the remaining cost of pro-
14 ducing the required data. Each of the joint data
15 developers shall submit adequate evidence of its
16 annual market participation to an independent
17 auditor for each of the years during the period of
18 the joint data development. Such independent
19 auditor shall be chosen by the joint data develop-
20 ers. The auditor's decisions and determinations
21 shall be final and binding on each of the joint data
22 developers. If additional data are required by the
23 Administrator under this paragraph, the same for-
24 mula and procedure specified in this paragraph
25 shall apply as if the subsequent request were the

1 initial request for data. Any registrant who shares
2 in the cost of producing the data shall be entitled
3 to receive a copy of the data, and to examine and
4 rely upon such data in support of maintenance of
5 such registration.

6 “(iii) Notwithstanding any other provision of
7 this Act, if a registrant, within the 180-day period
8 prescribed in clause (ii) of this subparagraph, fails
9 to participate in a joint data development arrange-
10 ment under that clause, or at any time fails to
11 comply with the terms of such an arrangement, or
12 if any of the joint data developers fails to take ap-
13 propriate steps to secure and submit the required
14 data, the Administrator shall issue a notice of
15 intent to suspend such registrant’s registration of
16 the pesticide for which additional data are re-
17 quired. The Administrator may include in the
18 notice of intent to suspend such provisions as the
19 Administrator deems appropriate concerning the
20 continued sale and use of existing stocks of such
21 pesticide. Any suspension proposed under this
22 subparagraph shall become final and effective at
23 the end of 30 days from receipt by the registrant
24 of the notice of intent to suspend, unless during
25 that time a request for hearing is made by a

1 person adversely affected by the notice, or the
2 registrant has satisfied the Administrator that the
3 registrant has complied fully with the require-
4 ments that served as a basis for the notice of
5 intent to suspend. If a hearing is requested, hear-
6 ing shall be conducted under section 6(d) of this
7 Act. The only matters for resolution at that hear-
8 ing shall be whether the Administrator had a
9 valid and reasonable basis for requiring the addi-
10 tional data, whether the registrant has failed to
11 take the action that served as the basis for the
12 notice of intent to suspend the registration of the
13 pesticide for which additional data is required, and
14 whether the Administrator's determination with
15 respect to the disposition of existing stocks is con-
16 sistent with this Act. If a hearing is held, a deter-
17 mination shall be made within 75 days after re-
18 ceipt of a request for such hearing, and the deci-
19 sion made after completion of such hearing shall
20 be final and shall not be subject to judicial review.
21 Any registration suspended under this subpara-
22 graph shall be reinstated by the Administrator if
23 the Administrator determines that the registrant
24 has complied fully with the requirements that

1 served as a basic for the suspension of the regis-
2 tration.

3 “(iv) Data submitted under this subparagraph
4 shall not be considered by the Administrator to
5 support any registration action or experimental
6 use permit on behalf of any person other than the
7 joint data developers for a period of 15 years after
8 the data are submitted, unless any such person
9 has reimbursed the joint data developers by
10 paying a share of the cost of producing the data
11 in proportion to the number of persons sharing in
12 such cost. Any such person shall upon payment
13 be considered to be an original participant and
14 shall share in all rights and be bound by all obli-
15 gations entered into by the original data develop-
16 ers. Such reimbursement shall be returned to the
17 original participants based on the percentage of
18 their overall monetary participation in the joint
19 data development arrangement.

20 “(v) Health and safety data submitted by a
21 registrant or applicant after September 30, 1978,
22 to replace data which are scientifically insufficient
23 under generally accepted good laboratory prac-
24 tices or test standards shall be considered to be
25 data requested by the Administrator under clause

1 (i) of this subparagraph. A registrant or applicant
2 undertaking such replacement studies shall notify
3 all other registrants of the active ingredient that
4 these replacement studies are being performed or
5 have been performed entitling each registrant to
6 participate in a joint data development arrange-
7 ment as provided in clause (ii) of this subpara-
8 graph. If other registrants decide to voluntarily
9 participate, the provisions of clauses (ii), (iii), and
10 (iv) of this subparagraph shall apply. Subsequent
11 applicants shall be entitled to participate as pro-
12 vided in subparagraph (iv).”;

13 (4) amending subsection (c)(2)(D) to read as fol-
14 lows:

15 “(D) EXEMPTION.—No applicant for registration
16 of a pesticide who proposes to purchase a registered
17 pesticide from another producer in order to formulate
18 such purchased pesticide into an end-use product shall
19 be required to—

20 “(i) submit or cite data pertaining to the
21 safety of such purchased products;

22 “(ii) offer to pay reasonable compensation
23 otherwise required by paragraph (1)(D) of this
24 subsection and subsection (h) for the use of any
25 such data; or

1 “(iii) share the cost of producing data re-
2 quired by paragraph (2)(B) of this subsection.”;

3 (5) amending subsection (c)(3) to read as follows:

4 “(3) TIME FOR ACTING WITH RESPECT TO AP-
5 PLICATION.—After receipt of the application, the Ad-
6 ministrator shall review the data as expeditiously as
7 possible, and either register the pesticide in accordance
8 with paragraph (5) or (7) of this subsection, or notify
9 the applicant in accordance with paragraph (6) of this
10 subsection of the Administrator’s determination that it
11 does not comply with the provisions of the Act.”;

12 (6) amending subsection (c)(8) by inserting the
13 designation (A) immediately before “Notwithstanding
14 any other provision of this Act”, and adding new sub-
15 paragraphs at the end thereof as follows:

16 “(B) At least 90 days prior to initiating a public
17 interim administrative review process, the Administra-
18 tor shall notify all affected registrants of the risks upon
19 which the proposed review will be based. In finally de-
20 termining whether to initiate a public interim review,
21 the Administrator shall consider any correcting or
22 clarifying data or other information submitted by a reg-
23 istrant, including data on human or environmental ex-
24 posure. If after giving notice to registrants under this
25 subparagraph, the Administrator determines that it is

1 not necessary to initiate a public interim review, then
2 the Administrator shall make the reasons therefor
3 available to the public.

4 “(C) The Administrator shall not by regulation or
5 otherwise utilize a public interim administrative review
6 process to abridge entitlement to a public hearing in
7 accordance with section 6 of this Act.

8 “(D) A decision by the Administrator not to
9 cancel or suspend the registration of a pesticide or any
10 use thereof or not to restrict the classification of a pes-
11 ticide, following an interim administrative review, shall
12 be subject to judicial review under section 16(b) of this
13 Act. Any final decision by the Administrator to such
14 effect shall be deemed ‘an order issued by the Adminis-
15 trator following a public hearing’ for the purpose of
16 section 16(b), and any person who has participated in
17 an interim administrative review shall be deemed ‘a
18 party to the proceedings’ for the purpose of that sub-
19 section.”;

20 (7) amending subsection (d)(1)(C)(ii) to read as fol-
21 lows:

22 “(ii) if the Administrator classifies a pesti-
23 cide, or one or more uses of a pesticide, for re-
24 stricted use because of a determination that its
25 use without additional regulatory restriction may

1 cause unreasonable adverse effects on the envi-
2 ronment, the pesticide shall be applied for any use
3 to which the determination applies only by or
4 under the direct supervision of a certified applica-
5 tor, or subject to such restrictions, including but
6 not limited to geographic, hydrogeologic, soil-spe-
7 cific or seasonal restrictions, as the Administrator
8 may provide by regulation. Any such regulation
9 shall be reviewable in the appropriate court of ap-
10 peals upon petition of a person adversely affected
11 within 60 days after issuance of the regulation in
12 final form.';

13 (8) adding at the end of subsection (g) the follow-
14 ing: "The Administrator shall furnish registrants rea-
15 sonable notice of when they must apply for reregistra-
16 tion of their products. If an application for reregistra-
17 tion of a product is not received within 90 days (or
18 such longer period as the Administrator may designate)
19 after such notice has been received, the Administrator
20 shall issue an order canceling the product's registra-
21 tion. The Administrator may include in the order such
22 provisions as the Administrator deems appropriate con-
23 cerning the continued sale and use of existing stocks of
24 the product. An order issued under this subsection

1 shall be a final agency action for purposes of section
2 16(a) of this Act.”; and

3 (9) adding a new subsection (h) to read as follows:

4 “(h)(1) With respect to applications approved in the
5 period beginning 18 months after the date of enactment of
6 the Federal Insecticide, Fungicide, and Rodenticide Act
7 Amendments of 1981, an applicant shall supply the data re-
8 quired for registration as set forth in this paragraph. The
9 applicant shall submit data or cite data previously submitted
10 to the Administrator, or use any combination of those two
11 methods, except to the extent that the applicant is precluded
12 from relying on data by the following provisions:

13 “(A) The following data shall not, without the
14 written permission of the original data submitter, be
15 relied on by any other applicant to support any appli-
16 cation for any registration action (conditional or uncon-
17 ditional) or experimental use permit during a period
18 commencing with the date the data are originally sub-
19 mitted and ending 15 years after the date the Adminis-
20 trator approves the original data submitter’s applica-
21 tion:

22 “(i) Data (other than defensive data) submit-
23 ted to support the application for the original reg-
24 istration of a pesticide product that contains a

1 new active ingredient and that was initially regis-
2 tered under this Act after September 30, 1978;

3 “(ii) Data submitted after September 30,
4 1978, to support an application to amend a regis-
5 tration of any pesticide by adding a new use, or
6 to register a pesticide with a new use, and that
7 pertain solely to such new use, regardless of the
8 date of the original registration of the pesticide or
9 its active ingredients; and

10 “(iii) Data (other than defensive data) sub-
11 mitted after the effective date of this amendment
12 to support an application for an experimental use
13 permit for a pesticide containing a new active in-
14 gredient;

15 “(B) During the period in which data of an origi-
16 nal data submitter are entitled to exclusive use protec-
17 tion under paragraph (A) of this subsection, any subse-
18 quent applicant also may obtain a registration for the
19 same new active ingredient or new use, or may obtain
20 a permit for the same experimental use, by indepen-
21 dently filing with the Administrator the data required
22 for registration or for the permit and by satisfying the
23 pertinent requirements of section 3(c)(5), 3(c)(7), or 5
24 of the Act. Data submitted by such subsequent appli-
25 cant shall be entitled to the same exclusive use protec-

1 tion as described in paragraph (A) of this subsection
2 but only for the duration of the period of exclusive use
3 remaining for data submitted by the original data sub-
4 mitter and can be relied upon by others only with the
5 written permission of the submitter of that data.

6 “(C) Data submitted pursuant to subsection
7 (c)(2)(B) of this section may be relied on by an appli-
8 cant only in accordance with the provisions of that sub-
9 section.

10 “(D) Data not described by subparagraph (A), (B),
11 or (C) of this paragraph and submitted by an applicant
12 or registrant after December 31, 1969, but on or
13 before September 30, 1978, to support an application
14 for registration, experimental use permit, amended reg-
15 istration, or to support or maintain in effect an existing
16 registration, or for reregistration may not, during the
17 15-year period following the date the data were origi-
18 nally submitted, be relied on in support of an applica-
19 tion by any other person (hereinafter referred to in this
20 subparagraph as the ‘applicant’) without the written
21 permission of the original data submitter, unless the
22 applicant has made an offer to compensate the original
23 data submitter and submitted such offer to the Admin-
24 istrator accompanied by evidence of delivery of the
25 offer to the original data submitter. The terms and

1 amount of compensation may be fixed by agreement
2 between the original data submitter and the applicant,
3 or, failing such agreement, binding arbitration under
4 this subparagraph. If, at the end of 90 days after the
5 date of delivery to the original data submitter of the
6 offer to compensate, the original data submitter and
7 the applicant have neither agreed on the amount and
8 terms of compensation nor agreed on a procedure for
9 reaching an agreement on the amount and terms of
10 compensation, either person may initiate binding arbitration
11 proceedings by requesting the Federal Mediation
12 and Conciliation Service to appoint an arbitrator
13 from the roster of arbitrators maintained by such Service.
14 The procedure and rules of the Service shall be
15 applicable to the selection of such arbitrator and to
16 such arbitration proceedings, and the findings and determination
17 of the arbitrator shall be final and conclusive,
18 and no official or court of the United States shall
19 have power or jurisdiction to review any such findings
20 and determination, except for fraud, misrepresentation,
21 or other misconduct by one of the parties to the arbitration
22 or the arbitrator where there is a verified complaint
23 with supporting affidavits attesting to specific instances
24 of such fraud, misrepresentation, or other misconduct.
25 The parties to the arbitration shall share

1 equally in the payment of the fee and expenses of the
2 arbitrator. If the Administrator determines that an
3 original data submitter has failed to participate in a
4 procedure for reaching an agreement or in an arbitra-
5 tion proceeding as required by this subparagraph, or
6 failed to comply with the terms of an agreement or ar-
7 bitration decision concerning compensation under this
8 subparagraph, the original data submitter shall forfeit
9 the right to compensation for the use of the data in
10 support of the application. Notwithstanding any other
11 provision of this Act, if the Administrator determines
12 that an applicant has failed to participate in a proce-
13 dure for reaching an agreement or in an arbitration
14 proceeding as required by this subparagraph, or failed
15 to comply with the terms of an agreement or arbitra-
16 tion decision concerning compensation under this sub-
17 paragraph, the Administrator shall deny the application
18 or cancel the registration of the pesticide in support of
19 which the data were used without further hearing.
20 Before the Administrator takes action under either of
21 the preceding two sentences, the Administrator shall
22 furnish to the affected person, by certified mail, notice
23 of intent to take action and allow 15 days from the
24 date of delivery of the notice for the affected person to
25 respond. If a registration is denied or canceled under

1 this subparagraph, the Administrator may make such
2 order as the Administrator deems appropriate concern-
3 ing the continued sale and use of existing stocks of
4 such pesticide. Registration action by the Administra-
5 tor shall not be delayed pending the fixing of compen-
6 sation;

7 “(E) Except as provided in subparagraphs (A)
8 through (D) of this paragraph, an applicant may rely
9 on any item of data without obtaining the permission of
10 the original data submitter and without offering to
11 compensate the original data submitter for the use of
12 such item of data.

13 “(F) Notwithstanding any other provision of this
14 Act, no provision of section 3 of this Act shall abridge
15 the right of an applicant or registrant to obtain a regis-
16 tration, reregistration, amended registration, or experi-
17 mental use permit (i) solely on the basis of data origi-
18 nally submitted by the applicant or registrant itself, (ii)
19 except as provided in subparagraphs (A) through (D) of
20 this paragraph, on the basis of previously submitted
21 data cited or submitted by an applicant or registrant,
22 or (iii) any combination of the foregoing; and the Ad-
23 ministrator shall not in any way abridge such right.

24 “(G) After the effective date of the Federal
25 Insecticide, Fungicide, and Rodenticide Act Amend-

1 ments of 1981, the Administrator may approve an ap-
2 plication only upon a determination that the application
3 is in compliance with subsections (c)(1)(D) and (h) of
4 this section. If an applicant has submitted or cited data
5 which are required for registration in a manner consist-
6 ent with subsections (c)(1)(D) and (h), the Administra-
7 tor may then review any other data in deciding wheth-
8 er the product causes (or would significantly increase
9 the risk of) unreasonable adverse effects on the envi-
10 ronment.

11 “(H) For the purposes of subsection (h)(1) of this
12 section, the term ‘data required for registration’ means
13 the minimum kinds and number of studies which the
14 Administrator would require in order to approve an ap-
15 plication for unconditional registration under subsection
16 (c)(5) of this section of a product with composition and
17 labeling identical or substantially similar to that of the
18 applicant’s product, including data sufficient to satisfy
19 guidelines issued under subsection (c)(2)(A) of this sec-
20 tion: *Provided*, That for purposes of paragraph
21 (1)(A)(ii), (1)(C), and (1)(D) of this subsection, the term
22 includes only data concerning the product’s active
23 ingredient(s): *Provided further*, That to the extent that
24 any such data have not been generated by any appli-
25 cant or registrant or have been determined by the Ad-

1 ministrator to be invalid, the provisions of subsection
2 (c)(7) of this section shall apply. Nothing contained in
3 subsection (h)(1) shall limit the provisions of subsection
4 (c)(2)(D) of this section. After the effective date of this
5 paragraph, an applicant for registration of a product
6 whose active ingredients and intended uses are identi-
7 cal or substantially similar to those of one or more al-
8 ready registered products need not submit or cite data
9 concerning any of the product's active ingredients
10 unless data of the same type for such ingredients
11 appear on the indexes prepared in accordance with
12 subparagraph (I) of this paragraph.

13 “(I) The Administrator shall compile, for each
14 active ingredient affected, an index comprised of each
15 item of data described by subparagraphs (A), (B), and
16 (C) of this paragraph. For each such item of data, the
17 list shall set forth the date item of data was originally
18 submitted, the identity of the original submitter, a brief
19 description of the kind of study that yielded the data,
20 and the subparagraph in subsection (h)(1) that describes
21 the data. The Administrator shall make the first such
22 set of indexes available for release to the public not
23 later than 1 year after the date of enactment of the
24 Federal Insecticide, Fungicide, and Rodenticide Act
25 Amendments of 1981. An item of data that was origi-

1 nally submitted to the Administrator on or before the
2 date of enactment of this subparagraph may be includ-
3 ed on any such index only if, not later than 180 days
4 after such date of enactment, the Administrator has re-
5 ceived from the original submitter of that item of data
6 a written statement setting forth the date the item of
7 data was originally submitted, a brief description of the
8 kind of study that yielded the data, the subparagraph
9 in this paragraph (1) that describes the data, the Envi-
10 ronmental Protection Agency data accession number (if
11 known), and the reasons why the item of data is enti-
12 tled to be included in the index. The Administrator
13 shall, not less frequently than semiannually, update the
14 indexes by adding any item of data described by sub-
15 paragraph (A), (B), or (C) of this paragraph and sub-
16 mitted after the effective date of these amendments,
17 and by deleting items of data which no longer are de-
18 scribed by subparagraphs (A), (B), (C), or (D) or which
19 the Administrator finds were incorrectly included on
20 the indexes. A decision by the Administrator to include
21 an item of data on such an index, or to exclude it,
22 shall be a final Agency action reviewable under section
23 16(a) of the Act.

24 “(J) At the request of an applicant for registration
25 of a product containing a particular active ingredient,

1 the Administrator shall require the original submitter
2 of any items of data which concern that active ingredi-
3 ent, but which are not included on any index compiled
4 under subparagraph (I) of this paragraph, to furnish a
5 report which briefly describes the type of study which
6 yielded each such item of data, states the date each
7 such item of data was originally submitted, and states
8 any accession numbers or other identifying information
9 used by the Agency to catalog the items of data.

10 “(K) Each applicant for registration under this
11 section, and each applicant for amendment of an exist-
12 ing registration to add a new use, shall include with
13 his application a list of the applicable data require-
14 ments and a list of the data he is submitting or citing
15 to satisfy each such requirement. After the Administra-
16 tor has approved an application, those lists shall be
17 available to the public. Any person who claims that the
18 applicant has incorrectly listed the applicable data re-
19 quirements, has not submitted or cited data sufficient
20 to satisfy those requirements, or otherwise has failed to
21 comply with subsection (c)(1)(D) or (h) of this section,
22 and who claims to have been adversely affected by the
23 approval of the application in his capacity as the origi-
24 nal submitter of data included on an index described by
25 subsection (h)(1)(I) of this section, may petition the Ad-

1 ministrator to hold a hearing to determine whether the
2 registration should be canceled. Such petition shall be
3 in writing and shall contain a detailed statement of
4 reasons why the registration should be canceled. Upon
5 receipt of the petition, the Administrator shall afford
6 the registrant a reasonable period of time, not to
7 exceed 60 days, to respond to the petitioner's allega-
8 tions. The Administrator shall then decide in writing
9 what action to take on the petition.

10 “(a) If the Administrator finds that the peti-
11 tion and any response show that there is no rea-
12 sonable possibility that a hearing would lead to
13 cancellation of the registration for the reasons set
14 forth in the petition, the Administrator shall deny
15 the petition. Any such denial shall be a final
16 Agency action for purposes of judicial review
17 under section 16(a) of the Act. The reviewing
18 court shall not allow discovery proceedings nor
19 receive testimony or evidence, and shall base its
20 review solely on the petition, the registrant's re-
21 sponse, the Administrator's decision, and the
22 pleadings and briefs filed with the court. If the
23 court finds that the Administrator's decision was
24 arbitrary, capricious, an abuse of discretion, or
25 otherwise not in accordance with law, the court

1 shall remand the matter to the Administrator for
2 purposes of holding a hearing under this para-
3 graph. If the court does not so find, the case shall
4 be dismissed.

5 “(b) If the Administrator finds that the peti-
6 tion and any response indicate that there is a rea-
7 sonable possibility that a hearing may lead to can-
8 cellation of the registration for the reasons set
9 forth in the petition, or if the Administrator is or-
10 dered by a court to hold a hearing, the Adminis-
11 trator shall issue a notice of intent to hold a hear-
12 ing to determine whether the product’s registra-
13 tion should be canceled, which notice shall be
14 published in the Federal Register and furnished
15 by certified mail to the registrant and the petition-
16 er. The hearing shall be held in the manner pro-
17 vided by section 6(d) of the Act: *Provided*, That
18 the provisions of that section regarding referral of
19 matters to a Committee of the National Academy
20 of Sciences shall not apply to such a hearing: *And*
21 *provided further*, That the petitioner shall have
22 the burden of proving that the registration should
23 be canceled. Review of the Administrator’s order
24 following such a hearing shall be governed by sec-
25 tion 16(b) of the Act. The provisions of this sub-

1 paragraph shall constitute the sole and exclusive
2 means of review, at the behest of any person
3 other than the Administrator, of the extent to
4 which an application for registration complies
5 with subsection (c)(1)(D) or (h) of this section, not-
6 withstanding the other provisions of this Act,
7 chapters 5 and 7 of title 5 of the United States
8 Code, or any other statute.

9 “(2) With respect to applications approved before expi-
10 ration of the 18-month period after enactment of the Federal
11 Insecticide, Fungicide, and Rodenticide Act Amendments of
12 1981, an applicant shall supply the data required for registra-
13 tion as set forth in this paragraph. An applicant shall file a
14 statement that includes, except as otherwise provided in sub-
15 section (c)(2)(D) of this section, if requested by the Adminis-
16 trator, a full description of the tests made and the results
17 thereof upon which the claims are based, or alternatively a
18 citation to data that appears in the public literature or that
19 previously had been submitted to the Administrator and that
20 the Administrator may consider in accordance with the fol-
21 lowing provisions:

22 “(A) with respect to pesticides containing active
23 ingredients that are initially registered under this Act
24 after September 30, 1978, data submitted to support
25 the application for the original registration of the pesti-

1 cide, or an application for an amendment adding any
2 new use to the registration and that pertains solely to
3 such new use, shall not, without the written permission
4 of the original data submitter, be considered by the
5 Administrator to support an application by another
6 person during a period of 15 years following the date
7 the Administrator first registers the pesticides: *Pro-*
8 *vided*, That such permissions shall not be required in
9 the case of defensive data;

10 “(B) except as otherwise provided in paragraph
11 (A) of this subsection, with respect to data submitted
12 after December 31, 1969, by an applicant or registrant
13 to support an application for registration, experimental
14 use permit, or amendment adding a new use to an ex-
15 isting registration, to support or maintain in effect an
16 existing registration, or for reregistration, the Adminis-
17 trator may, without the permission of the original data
18 submitter, consider any such item of data in support of
19 an application by any other person (hereinafter in this
20 subparagraph referred to as the ‘applicant’) within the
21 15-year period following the date the data were origi-
22 nally submitted only if the applicant has made an offer
23 to compensate the original data submitter and submit-
24 ted such offer to the Administrator accompanied by
25 evidence of delivery to the original data submitter of

1 the offer. The terms and amount of compensation may
2 be fixed by agreement between the original data sub-
3 mitter and the applicant, or, failing such agreement,
4 binding arbitration under this subparagraph. If, at the
5 end of 90 days after the date of delivery to the original
6 data submitter of the offer to compensate, the original
7 data submitter and the applicant have neither agreed
8 on the amount and terms of compensation nor on a
9 procedure for reaching an agreement on the amount
10 and terms of compensation, either person may initiate
11 binding arbitration proceedings by requesting the Fed-
12 eral Mediation and Conciliation Service to appoint an
13 arbitrator from the roster of arbitrators maintained by
14 such service. The procedure and rules of the Service
15 shall be applicable to the selection of such arbitrator
16 and to such arbitration proceedings, and the findings
17 and determination of the arbitrator shall be final and
18 conclusive, and no official or court of the United States
19 shall have power or jurisdiction to review any such
20 findings and determination, except for fraud, misrep-
21 sentation, or other misconduct by one of the parties to
22 the arbitration or the arbitrator where there is a veri-
23 fied complaint with supporting affidavits attesting to
24 specific instances of such fraud, misrepresentation, or
25 other misconduct. The parties to the arbitration shall

1 share equally in the payment of the fee and expenses
2 of the arbitrator. If the Administrator determines that
3 an original data submitter has failed to participate in a
4 procedure for reaching an agreement or in an arbitra-
5 tion proceeding as required by this paragraph, or failed
6 to comply with the terms of an agreement or arbitra-
7 tion decision concerning compensation under this para-
8 graph, the original data submitter shall forfeit the right
9 to compensation for the use of the data in support of
10 the application. Notwithstanding any other provision of
11 this Act, if the Administrator determines that an appli-
12 cant has failed to participate in a procedure for reach-
13 ing an agreement or in an arbitration proceeding as re-
14 quired by this subparagraph, or failed to comply with
15 the terms of an agreement or arbitration decision con-
16 cerning compensation under this paragraph, the Ad-
17 ministrator shall deny the application or cancel the
18 registration of the pesticide in support of which the
19 data were used without further hearing. Before the
20 Administrator takes action under either of the preced-
21 ing two sentences, the Administrator shall furnish to
22 the affected person, by certified mail, notice of intent
23 to take actions and allow 15 days from the date of de-
24 livery of the notice for the affected person to respond.
25 If a registration is denied or canceled under this sub-

1 paragraph, the Administrator may make such order as
2 the Administrator deems appropriate concerning the
3 continued sale and use of existing stocks of such pesti-
4 cide. Registration action by the Administrator shall not
5 be delayed pending the fixing of compensation;

6 “(C) after expiration of any period of exclusive
7 use and any period for which compensation is required
8 for the use of an item of data under paragraphs (A)
9 and (B) of this subsection, the Administrator may con-
10 sider such item of data in support of an application by
11 any other applicant without the permission of the origi-
12 nal data submitter and without an offer having been
13 received to compensate the original data submitter for
14 the use of such item of data.”.

15 CANCELLATION AND CHANGE IN CLASSIFICATION

16 SEC. 4. Section 6(b) of the Federal Insecticide, Fungi-
17 cide, and Rodenticide Act is amended by—

18 (1) amending clauses (1) and (2) of the first sen-
19 tence to read as follows:

20 “(1) to cancel or phase out its registration, or to
21 change its classification, together with the reasons (in-
22 cluding the factual basis) for such action, or

23 “(2) to hold a hearing to determine whether or
24 not its registration should be canceled or phased out,
25 or its classification changed.”;

1 (2) striking out the third sentence and inserting in
2 lieu thereof the following: "In determining whether to
3 issue any such notice, the Administrator shall include
4 among the factors to be taken into account the impact
5 of the action proposed in such notice on production and
6 prices of agricultural commodities, retail food prices,
7 and otherwise on agricultural producers, and on the
8 agricultural economy. The determination of such im-
9 pacts shall be based on biologic and economic assess-
10 ments, including but not limited to any prepared by the
11 Department of Agriculture. Such assessments shall be
12 used by the Administrator in formulating and assessing
13 the impacts of the proposed regulatory action."; and

14 (3) striking out the last sentence and inserting in
15 lieu thereof the following: "In taking any final action
16 under this subsection, the Administrator shall consider
17 restricting a pesticide's use or uses as an alternative to
18 cancellation and shall fully explain the reasons for
19 these restrictions, and include among those factors to
20 be taken into account the impact of such final action
21 on production and prices of agricultural commodities,
22 retail food prices, and otherwise on agricultural pro-
23 ducers and on the agricultural economy, and the Ad-
24 ministrator shall publish in the Federal Register a
25 notice of availability of an analysis of such impacts. In

1 preparing the final analysis of such impacts, the Ad-
2 ministrator shall fully consider all comments on the
3 proposal, including those provided by the Secretary.”.

4 PROTECTION OF TRADE SECRETS AND OTHER
5 INFORMATION

6 SEC. 5. Section 10 of the Federal Insecticide, Fungi-
7 cide, and Rodenticide Act is amended by—

8 (1) amending subsection (a) to read as follows:

9 “(a) IN GENERAL.—In submitting data required by this
10 Act, the data submitter must clearly mark portions thereof
11 which in the opinion of the data submitter are trade secrets
12 or commercial or financial information, explain why each
13 marked portion is not required to be disclosed under subsec-
14 tion (d)(1) of this section, and submit such marked materials
15 separately from the other material required under this Act.”;

16 (2) amending subsection (c) to read as follows:

17 “(c) DISPUTES.—If the Administrator proposes to re-
18 lease for inspection information which the applicant or regis-
19 trant believes to be protected from disclosure under subsec-
20 tion (b) of this section, including information which the appli-
21 cant or registrant claims is of the type described in clauses
22 (A), (B), or (C) of subsection (d)(1) of this section, the Admin-
23 istrator shall notify the applicant or registrant, in writing, by
24 certified mail. The Administrator shall not thereafter make
25 available for inspection such data until 30 days after receipt

1 of the notice by the applicant or registrant. During this
2 period, the applicant or registrant may institute an action in
3 an appropriate district court for a declaratory judgment as to
4 whether such information is subject to such protection from
5 disclosure.”;

6 (3) amending subsection (d)(1) to read as follows:

7 “(d) LIMITATIONS.—

8 “(1) All information concerning the objectives,
9 methodology, results, or significance of any test or ex-
10 periment performed on or with a registered or previ-
11 ously registered pesticide or its separate ingredients,
12 impurities, or degradation products, and any informa-
13 tion concerning the effects of such pesticide on any or-
14 ganism or the behavior of such pesticide in the envi-
15 ronment, including but not limited to, data on safety to
16 fish and wildlife, humans and other mammals, plants,
17 animals, and soil, and studies on persistence, transloca-
18 tion and fate in the environment, and metabolism, shall
19 be available for disclosure to the public as provided in
20 subparagraphs (A) to (D) of paragraph (2) of this sub-
21 section: *Provided*, That the use of such data for any
22 registration purpose shall be governed by section 3 of
23 this Act. This paragraph does not authorize the disclo-
24 sure of any information as to—

1 “(A) manufacturing or quality control proc-
2 esses,

3 “(B) the details of any methods for testing,
4 detecting, or measuring the quantity of any delib-
5 erately added inert ingredient of a pesticide, or

6 “(C) the identity or percentage quantity of
7 any deliberately added inert ingredient of a pesti-
8 cide, unless the Administrator has first determined
9 that disclosure is necessary to protect against an
10 unreasonable risk of injury to health or the envi-
11 ronment.

12 Before disclosing any information under this paragraph (other
13 then information which has already been made public or
14 which the applicant has previously determined as not con-
15 taining trade secret or commercial or financial information),
16 the Administrator shall afford the data submitter that origi-
17 nally submitted the information a reasonable period of time,
18 not to exceed 60 days from the date of receipt by the appli-
19 cant or registrant of a request by the Administrator, to iden-
20 tify any portions of the information the applicant or registrant
21 claims are described by clause (A), (B), or (C) of this para-
22 graph and to substantiate such claims. If no claim is made (or
23 if the claim is not reasonably substantiated) within the period
24 afforded, the information shall be made available in accord-
25 ance with this section. The provisions of subsection (c) of this

1 section shall apply to disputes with respect to information
2 which the Administrator finds not to be to the type described
3 by clause (A), (B), or (C) of this paragraph.”;

4 (4) redesignating subsections (d)(2) and (d)(3) as
5 subsections (d)(3) and (d)(4), respectively;

6 (5) adding a new subsection (d)(2) to read as fol-
7 lows:

8 “(d)(2) The Administrator shall make information that
9 may be disclosed under subsection (d)(1) of this section avail-
10 able through Environmental Protection Agency reading
11 rooms to be located at Environmental Protection Agency na-
12 tional headquarters and each of its regional offices. Such in-
13 formation shall be transmitted by the Administrator to the
14 regional offices as requested. All copies of data disclosable or
15 available in or from an Environmental Protection Agency
16 reading room shall remain under the control of the United
17 States Government.

18 “(A) Except for employees or agents of any
19 person engaged in, or which intends to engage in, the
20 production or registration of pesticides, or any other
21 person which intends to deliver data in violation of this
22 section to any employee or agent of any person en-
23 gaged in the production or registration of pesticides, all
24 members of the public, including employees of the
25 United States and agencies of State governments, shall

1 be permitted access to the reading rooms established
2 pursuant to this section: *Provided*, That employees, or
3 their agents, having jurisdiction over pesticide matters
4 in any agency of the United States or a State govern-
5 ment shall have access to the reading room even
6 though the agency may be a pesticide registrant or
7 producer: *And provided further*, That designated repre-
8 sentatives of groups of employees, or individual em-
9 ployees, of pesticide producers who seek access to in-
10 formation available for disclosure in connection with
11 providing advice on the health effects of the pesticide
12 or its ingredients to the employees shall be permitted
13 access to the reading room.

14 “(B) Any person described in subparagraph (A)
15 who wishes to make use of the reading room for any
16 purpose shall—

17 “(i) state in writing the name, address, and
18 occupation of that person and any other person
19 which the person is representing, and a descrip-
20 tion of the information, if any, which the person
21 seeks to remove or copy;

22 “(ii) sign a statement that such person does
23 not seek access to information for the purpose of
24 informing any person engaged in the production
25 or registration of pesticides of the contents of such

1 information and will not cause such information to
2 be disclosed to any such person or its agents or
3 employees, except for information which may be
4 copied under subparagraph (C) of this paragraph,
5 and except to the extent such disclosure is made
6 in compliance with paragraph (G) of this subsection;
7 and

8 “(iii) comply with rules and procedures established by the Administrator consistent with the
9 provisions of this section.
10

11 “(C) Subject to the requirements of subparagraphs
12 (B), (D), (E), and (F) of this paragraph, any person
13 having access to a reading room may—

14 “(i) take notes on any information available
15 for disclosure in the reading room;

16 “(ii) obtain on request from the Environmental Protection Agency at the reading room a copy
17 of any charts, graphs, or tables containing statistical data that may be contained in any study available
18 for disclosure in the reading room;
19

20 “(iii) remove any notes and copies of the
21 foregoing charts, graphs, or tables from the reading
22 room and retain such material without returning it to the reading room; and
23
24

1 “(iv) borrow and remove from the reading
2 room any other documents containing information
3 available for disclosure under this section.

4 “(D) Authorized representatives of agencies of the
5 Federal and State governments not also employed by
6 or acting on behalf of a person engaged in the produc-
7 tion or registration of pesticides may remove any infor-
8 mation available for disclosure from the reading room,
9 including complete studies, after complying with the
10 requirements of paragraph (B).

11 “(E) United States medical practitioners and
12 health and safety professionals, including those desig-
13 nated by a labor union or designated by an employee
14 of a pesticide producer, and any other individual or or-
15 ganization not otherwise restricted from access to a
16 reading room, may apply to the Administrator for per-
17 mission to borrow and remove any information availa-
18 ble in a reading room, including complete studies. The
19 Administrator shall grant such permission within not
20 more than 30 days after the application is received
21 unless the Administrator has determined that the
22 person should be denied permission pursuant to the
23 protections afforded data in subparagraph (G) of this
24 paragraph. The Administrator shall forward a copy of
25 the application to the business entity originating the in-

1 formation requested, provide that business entity ten
2 days to transmit to the Administrator any factual infor-
3 mation related to the application that the entity be-
4 lieves the Administrator should consider before acting
5 upon the application, and inform the entity regarding
6 the Administrator's intention to approve the application
7 15 days before the actual release of the information
8 from the reading room. The Administrator's decision
9 with regard to an application for permission to borrow
10 and remove documents containing information available
11 for disclosure in a reading room shall be final and not
12 subject to judicial review.

13 “(F) Once a person has been granted permission
14 to borrow and remove documents containing informa-
15 tion available for disclosure in a reading room, such
16 person shall not be required to reapply for permission
17 to borrow and remove material as long as that person
18 has complied with the rules and regulations prescribed
19 by the Administrator in subparagraph (B)(iii) of this
20 paragraph. In addition, such person may request and
21 receive and return documents containing information
22 borrowed from a reading room through registered mail.

23 “(G) Except as otherwise provided in this subpar-
24 agraph, all documents containing information available
25 for disclosure borrowed from a reading room shall be

1 returned to that reading room and shall not be dis-
2 closed or made available in any manner by the borrow-
3 er to any other person. Any person that obtains from
4 the reading room a copy of any charts, graphs, or
5 tables containing statistical data or makes notes based
6 upon any study available for disclosure in the reading
7 room need not return such copies and notes and may
8 use such material for any purpose including, but not
9 limited to, participation in administrative, judicial, or
10 legislative proceedings, publication, medical treatment,
11 or evaluating potential health effects of a pesticide.
12 Except for charts, graphs, and tables containing statis-
13 tical data and notes based upon the available studies,
14 no person may reproduce in any manner any material
15 borrowed from the reading room. For the purpose of
16 this paragraph, notes shall not include a verbatim tran-
17 script of an entire study. If any person violates the
18 provisions of this paragraph, that person and any other
19 person upon whose behalf he or she was acting, may
20 be debarred by the Administrator from any further
21 access to the reading rooms.”; and

22 (5) amending subsections (f) and (g) to read as fol-
23 lows:

24 “(f) DISCLOSURE TO PESTICIDE PRODUCERS.—

1 “(1) Except as otherwise provided in this section,
2 the Administrator shall not knowingly allow access to
3 an Environmental Protection Agency reading room or
4 otherwise disclose information submitted by an appli-
5 cant or registrant under this Act to any employee or
6 agent of any person engaged in, or who intends to
7 engage in, the production of pesticides or to any other
8 person who intends to disclose such data to such
9 person, unless the data submitter has consented to
10 such disclosure. Notwithstanding any other provision of
11 this section, during administrative adjudicatory hear-
12 ings or court litigation a party may, pursuant to an ap-
13 propriate protective order issued by the court or pre-
14 siding administrative official, examine and obtain a
15 copy of data submitted by another person (other than
16 data described by subsections (d)(1) (A) through (C) of
17 subsection (d)(3) of this section), if the party’s access to
18 the data is found to be necessary in order to allow the
19 party to participate fully in the hearing or litigation.

20 “(2) The Administrator shall maintain and make
21 available upon request records containing the informa-
22 tion required by subsection (d)(2)(B)(i) of this section.
23 When data are borrowed and removed from a reading
24 room under this section, the Administrator shall inform
25 the data submitter of the identity of the data and the

1 information furnished by the borrower under subsection
2 (d)(2)(B)(i) of this section.

3 “(g) INTERNATIONAL AGREEMENTS.—Notwithstand-
4 ing any other provision of law—

5 “(1) The Administrator shall not make available
6 for public inspection any document or information con-
7 cerning pesticides if (A) the Administrator obtained the
8 document or information from the government of an-
9 other country (or from an international organization of
10 countries), (B) the government or international organi-
11 zation required the Administrator to agree not to dis-
12 close the document or information to the public as a
13 condition of furnishing it to the Administrator, (C) the
14 Administrator could not otherwise obtain the document
15 or information, and (D) the government or international
16 organization continues to demand that the document or
17 information not be made available for public inspection.

18 “(2) Except for information describing subsection
19 (d)(1)(A) or (d)(2) of this section, the Administrator
20 may disclose information otherwise entitled to protec-
21 tion under this section to the government of another
22 country if that government furnishes assurances ac-
23 ceptable to the Administrator that the government:

24 “(A) will not further disclose the information
25 without the consent of either the Administrator or

1 the applicant or registrant which submitted the in-
2 formation; and

3 “(B) will not use the information to support
4 any decision to grant any license, permit, or other
5 action which allows the production, sale, or distri-
6 bution of a pesticide under that country’s laws.”.

7 UNLAWFUL ACTS

8 SEC. 6. Section 12(a)(2) of the Federal Insecticide, Fun-
9 gicide, and Rodenticide Act is amended by—

10 (1) striking out “or” at the end of clause (O);

11 (2) striking out the period at the end of clause (P)
12 and inserting in lieu thereof “, or”; and

13 (3) adding a new subparagraph at the end thereof
14 as follows:

15 “(Q) to discharge from employment or otherwise
16 adversely affect the employment status of any person
17 because of that person’s exercising rights under this
18 Act or filing complaints concerning alleged violations
19 of this Act,”.

20 PENALTIES

21 SEC. 7. Section 14 of the Federal Insecticide, Fungi-
22 cide, and Rodenticide Act is amended by—

23 (1) redesignating subsections (a)(3), (a)(4), and
24 (a)(5) as subsections (a)(4), (a)(5), and (a)(6), respec-
25 tively;

1 (2) adding a new subsection (a)(3) to read as fol-
2 lows:

3 “(a)(3) DISCLOSURE OF DATA TO PESTICIDE PRODUC-
4 ERS.—Any person granted access to data pursuant to section
5 10(d) that violates the provisions of that subsection or who
6 knowingly accepts data prohibited from disclosure under sec-
7 tion 10(d) may be assessed a civil penalty by the Administra-
8 tor of not more than \$100,000 for each document or study
9 obtained or used in violation of section 10.”;

10 (3) amending subsection (a)(4), as redesignated, to
11 read as follows:

12 “(a)(4) DETERMINATION OF PENALTY.—In determin-
13 ing the amount of the penalty, the Administrator shall con-
14 sider the appropriateness of such penalty to the size of the
15 business of the person charged, the effect on the person’s
16 ability to continue in business, and the gravity of the viola-
17 tion. Whenever the Administrator finds that a violation oc-
18 curred despite the exercise of due care or did not cause sig-
19 nificant harm to health or the environment, or in the case of
20 a violation as described in paragraph 3 of this subsection did
21 not cause significant harm to the registrant that originated
22 the data, the Administrator may issue a warning in lieu of
23 assessing a penalty.”; and

24 (4) amending subsection (b)(3) to read as follows:

25 “(b)(3) DISCLOSURE OF INFORMATION.—

1 “(A) Any person, who, with intent to defraud,
2 uses or reveals information relative to formulas of
3 products acquired under the authority of section 3,
4 shall be fined not more than \$100,000, or imprisoned
5 for not more than 3 years, or both.

6 “(B) Any person granted access to data under
7 section 10(d) that knowingly allows the data to be sold
8 or otherwise made available contrary to the provisions
9 of section 10 of this Act to any other person engaged
10 in the production of pesticide products or any employee
11 or agent thereof in violation of such section shall be
12 fined not more than \$100,000 or imprisoned for not
13 more than 1 year or both.

14 “(C) Any officer or employee of the United States
15 or any State or former officer or employee of the
16 United States or any State, who, by virtue of such em-
17 ployment or official position has obtained possession of,
18 or has access to material the disclosure of which is
19 prohibited by section 10, and who, knowing that dis-
20 closure of such material is prohibited by such section,
21 willfully discloses the material in any manner to any
22 person not entitled to receive it, shall be fined not
23 more than \$100,000 or imprisoned for not more than 1
24 year, or both. For the purpose of this subparagraph,
25 any contractor with the United States who is furnished

1 information as authorized by section 10(e), or any em-
2 ployee of any such contractor, shall be considered to be
3 an employee of the United States.

4 “(D) Section 1905 of title 18 of the United States
5 Code shall not apply with respect to the publishing, di-
6 vulging, disclosure, or making known of, or making
7 available, information reported or otherwise obtained
8 under this Act. Nothing in this Act shall preempt any
9 civil remedy under State or Federal law for any disclo-
10 sure wrongful under section 10.”.

11 JUDICIAL REVIEW

12 SEC. 8. Section 16 of the Federal Insecticide, Fungi-
13 cide, and Rodenticide Act is amended by adding at the end
14 thereof a new subsection as follows:

15 “(e) Any person claiming to be aggrieved by misuse of a
16 pesticide may bring suit in a United States district court
17 having jurisdiction of the parties for damages, equitable
18 relief, and reasonable attorney’s fees and costs, including
19 expert witness fees.”.

20 EXPORTS

21 SEC. 9. Section 17(b) of the Federal Insecticide, Fungi-
22 cide, and Rodenticide Act is amended to read as follows:

23 “(b) CANCELLATION NOTICES FURNISHED TO FOR-
24 EIGN GOVERNMENTS.—Whenever a registration, or a can-
25 cellation or suspension of the registration of a pesticide be-

1 comes effective, or ceases to be effective, the Administrator
2 shall transmit through the State Department notification
3 thereof to the governments of other countries and to appro-
4 priate international agencies. Subject to the restrictions on
5 disclosures of trade secrets as specified in section 10(d)(1)
6 (A), (B), and (C), such notification shall, upon request, in-
7 clude all information related to the cancellation or suspension
8 of the registration of the pesticide and information concerning
9 other pesticides that are registered under section 3 of this
10 Act and that could be used in lieu of such pesticide.”.

11 STATE COOPERATION, AID, AND TRAINING

12 SEC. 10. Effective with the fiscal year beginning Octo-
13 ber 1, 1982, section 23 of the Federal Insecticide, Fungicide,
14 and Rodenticide Act is amended by—

15 (1) striking out in subsection (a) the second and
16 third sentences; and

17 (2) adding at the end thereof a new subsection as
18 follows:

19 “(d)(1) There are authorized to be appropriated for each
20 fiscal year such sums as may be necessary for the Adminis-
21 trator to provide through cooperative agreements an amount
22 equal to 50 percent of the anticipated cost of each State or
23 Indian tribe, as agreed under such cooperative agreements, of
24 conducting training programs for certification of applicators
25 during such fiscal year pursuant to subsection (c) of this sec-

1 tion. Funds will be distributed among States and Indian
2 tribes on a formula basis, as developed cooperatively between
3 the Secretary of Agriculture and the Administrator.

4 “(2) There are also authorized to be appropriated for
5 each fiscal year such sums as may be necessary for the Ad-
6 ministrator to provide through cooperative agreements an
7 amount equal to 50 percent of the anticipated cost to each
8 State or Indian tribe, as agreed under such cooperative
9 agreements, of conducting pesticide certification and licensing
10 programs during such fiscal year, and in the case of a State,
11 for administering the State plan of each State approved
12 under section 4(a)(2). Funds shall be distributed among the
13 States on a formula basis as specified by the Administrator.

14 “(3) The total amount authorized to be appropriated
15 under paragraphs (2) and (3) of this subsection may not
16 exceed \$4,000,000 for each fiscal year. If funds sufficient to
17 pay 50 percent of the costs under paragraph (2) or (3) of this
18 subsection for any year are not appropriated, the share of
19 each State and Indian tribe shall be reduced in a like propor-
20 tion in allocating available funds.

21 “(4) States conducting training and certification pro-
22 grams under State plans shall coordinate such programs to
23 assure that standards for certification of applicators of pesti-
24 cides are attained and maintained as prescribed by the Ad-
25 ministrator under section 4 of this Act.”.

1 AUTHORITY OF THE STATES

2 SEC. 11. Section 24 of the Federal Insecticide, Fungi-
3 cide, and Rodenticide Act is amended by—

4 (1) amending subsection 24(a) to read as follows:

5 “(a)(1) A State may regulate the sale or use of any fed-
6 erally registered pesticide or device in the State, but only if
7 and to the extent that the regulation does not permit any sale
8 or use prohibited by this Act.

9 “(2) If a State in regulating the sale or use of a federally
10 registered pesticide or device in the State wishes health and
11 safety data submitted for review in connection with a State
12 registration or approval, the following shall apply:

13 “(A) With respect to data previously submitted in
14 support of the Federal registration, the State may re-
15 quest the applicant to submit such data to the State for
16 review, and if the applicant does not provide the State
17 such data as is requested, the Administrator shall make
18 the data available to the State, subject to the provi-
19 sions of section 10. At the option of the State, the data
20 may be obtained from the Administrator under the pro-
21 visions of section 10 without first making the request
22 to the registrant.

23 “(B)(i) A State may require submission of addi-
24 tional data with respect to any special local concerns
25 relating to either an increased risk of any unreasonable

1 adverse effect on the environment from the uses of
2 such pesticide or device in the State, or a reduced effi-
3 cacy of the pesticide or device in the State for the uses
4 for which the application to the State is made: *Pro-*
5 *vided*, That the State shall give the applicant written
6 notice of the purpose and justification of the require-
7 ment.

8 “(ii) In the case of a nonrestricted use or general
9 use pesticide, as classified by the Administrator pursu-
10 ant to section 3(d), except for pesticides utilized in the
11 production of a commercial food, feed or fiber, crop, if
12 the applicant wishes to contest the request for data de-
13 scribed in clause (i) of this subparagraph, the applicant
14 may submit the request to the Administrator for
15 review. In reviewing the request, if the Administrator
16 determines that there is a Federal interest, such that
17 the request should be made by the Administrator, the
18 Administrator shall require the applicant to submit the
19 additional data under section 3(c)(2)(B) of this Act. The
20 State’s determination of a special local concern pursu-
21 ant to this section shall not be subject to review by the
22 Administrator but shall be subject to judicial review.
23 The Administrator may overrule or modify the State
24 request for additional data if the Administrator deter-
25 mines that the request is arbitrary or capricious, or de-

1 termines that there exist sources of comparable data
2 that would be available to the State for the purposes of
3 satisfying its request and so notifies the State. The
4 State and the applicant may submit to the Administra-
5 tor any additional information pertaining to the data
6 request. The Administrator shall publish in the Federal
7 Register the basis for any determination that overrules
8 or modifies the State request. A State may obtain judi-
9 cial review of a decision by the Administrator to over-
10 rule or modify that State's data request. The applicant
11 may seek judicial review of the determination of the
12 State to require the data either before or after the
13 matter has been submitted to the Administrator for
14 review and the Administrator has made a determina-
15 tion: *Provided*, That the Administrator shall not be a
16 party to any such action.

17 "(iii) In other cases involving special local con-
18 cerns, any applicant that wishes to contest the request
19 for additional data shall be subject to the provisions of
20 State law.

21 "(C) Any request for data that does not relate to
22 special local concerns as described in subparagraph (B)
23 of this paragraph, and that was not previously submit-
24 ted to the Administrator in support of the Federal reg-
25 istration shall be reviewable by the Administrator. In

1 reviewing the request, if the Administrator determines
2 that there is a Federal interest, such that the request
3 should be made by the Administrator, the Administra-
4 tor shall require the applicant to submit the additional
5 data under section 3(c)(2)(B) of this Act. The Adminis-
6 trator may otherwise disapprove the request if the Ad-
7 ministrator determines that the request is arbitrary or
8 capricious or that there is no reasonable basis for
9 making use of the data in connection with a State de-
10 termination as to registration or approval of the pesti-
11 cide. Any request for data under this subparagraph
12 shall be submitted to the applicant and at the same
13 time a copy shall be forwarded to the Administrator. If
14 the Administrator has not taken any action within 60
15 days after receipt of the request for additional data, or
16 15 days after receipt by the Administrator of any addi-
17 tional information that may be requested of the State,
18 approval of the request by the State shall be presumed.
19 Any determination by the Administrator shall be final
20 and not subject to judicial review.

21 "(3)(A) Except as to applications for which a State has
22 requested health and safety data that relate to special local
23 concerns as described in paragraph (a)(2)(B) of this subsec-
24 tion, if a State receives an application for a registration, the
25 registration shall be granted pending further review if the

1 State has not affirmatively approved or disapproved the ap-
2 plication within—

3 “(i) 60 days after receipt of the application or
4 such lesser period as may be provided in State law, or

5 “(ii) if the application for registration involves a
6 restricted use pesticide, or a general use pesticide uti-
7 lized in the production of a commercial food crop, and
8 the use is a new use of the pesticide or device within a
9 State, or the pesticide contains a new active ingredi-
10 ent, for which the State has not previously granted ap-
11 proval, within 120 days or such lesser period as may
12 be provided by State law after receipt of the applica-
13 tion accompanied by all data, if any, required by State
14 law and regulations at the time of application, or with
15 appropriate reference to data previously submitted or
16 cited by the applicant.

17 The provisions of this paragraph shall apply both
18 to cases where the State has made a request for addi-
19 tional data, as well as to cases where the State had
20 not made such a request.

21 “(B) With respect to applications for which a State has
22 requested health and safety data that relate to special local
23 concerns as described in subsection (a)(2)(B) of this section, a
24 State may prohibit or restrict the sale or use of the pesticide
25 or device within a State for which the application is made

1 pending development, submission, and review of the health
2 and safety data.

3 “(C) A State may not restrict the sale or use of a pesti-
4 cide or device within the State for failure of the applicant to
5 submit health and safety data requested by the State to the
6 extent the Administrator has disapproved such request under
7 paragraphs (2)(B) or (2)(C) of this subsection.

8 “(4) The district courts of the United States shall have
9 jurisdiction to review determinations of the Administrator
10 under this subsection and of the States under subsection
11 (a)(2)(B)(ii) of this section that are subject to judicial review
12 and shall have jurisdiction to enforce and to prevent and re-
13 strain violations of the provisions of paragraph (3)(A) of this
14 subsection.”.

15 SCIENTIFIC ADVISORY PANEL

16 SEC. 12. Section 25(d) of the Federal Insecticide, Fun-
17 gicide, and Rodenticide Act is amended by—

18 (1) amending the fourth sentence to read as fol-
19 lows: “The comments, evaluations, and recommenda-
20 tions of the advisory panel submitted under this subsec-
21 tion and the response of the Administrator shall be
22 published in the Federal Register in the same manner
23 as provided for publication of the comments of the Sec-
24 retary of Agriculture under such sections.”; and

1 (2) striking out in the penultimate sentence "Sep-
2 tember 30, 1981" and inserting in lieu thereof "Sep-
3 tember 30, 1983".

4 SAFE WORKING CONDITIONS

5 SEC. 13. Section 25 of the Federal Insecticide, Fungi-
6 cide, and Rodenticide Act is amended by adding at the end
7 thereof a new subsection as follows:

8 “(e) The Congress hereby finds and declares that it is
9 necessary to provide for the safe use of pesticides and for safe
10 working conditions for farmworkers, pest control applicators,
11 and other persons handling, storing, or applying pesticides or
12 working or living in and around pesticide treated areas. To
13 this end, the Administrator shall adopt guidelines pursuant to
14 the procedures set forth in this section as soon as practicable,
15 but in no event later than one year after the date of enact-
16 ment of the Federal Insecticide, Fungicide, and Rodenticide
17 Act Amendments of 1981 to establish minimum field reentry
18 standards and posting of such standards, to protect other per-
19 sons near pesticide treated areas, to establish minimum re-
20 quirements for storing, warehousing, and disposal of pesti-
21 cides and pesticide containers, and for the other purposes
22 specified in the first sentence of this subsection.”.

1 RECORDS CONCERNING STATE ENFORCEMENT

2 SEC. 14. Section 26(a)(3) of the Federal Insecticide,
3 Fungicide, and Rodenticide Act is amended to read as fol-
4 lows:

5 “(3) will keep such records necessary to provide
6 an annual programmatic review showing compliance
7 with paragraphs (1) and (2) of this subsection. Where
8 emergency conditions exist, reports of emergency ac-
9 tions taken shall be provided to the Administrator at
10 the earliest practical date.”.

11 STATE ENFORCEMENT ACTION

12 SEC. 14. Section 27(a) of the Federal Insecticide, Fun-
13 gicide, and Rodenticide Act is amended to read as follows:

14 “(a) Upon receipt of any complaint or other information
15 alleging or indicating a significant violation of the pesticide
16 use provisions of this Act, the Administrator shall refer the
17 matter to the appropriate State officials for their investiga-
18 tion of the matter consistent with the requirements of this
19 Act. As soon as practicable after a complaint is filed and in
20 no event later than 30 days, the State must commence ap-
21 propriate investigative action, and if within 120 days, the
22 State has not commenced appropriate enforcement action,
23 the Administrator may act upon the complaint of information
24 to the extent authorized under this Act: *Provided*, That in
25 the event of a complaint pertaining to a violation involving an

1 alleged injury to an agricultural worker, the State must un-
2 dertake an appropriate field investigative action as soon as
3 possible, and in no event later than 5 days after receipt of the
4 complaint, if a longer period of delay in investigative action
5 would jeopardize the gathering of scientific information
6 needed in order to substantiate or refute the substance of the
7 complaint.”.

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Statement of
Kirk A. Johnson
Center for Science in the Public Interest
Washington, D.C.
to the
Subcommittee on Department Operations, Research,
and Foreign Agriculture
U.S. House of Representatives
February 4, 1982

Mr. Chairman and members of the subcommittee, my name is Kirk Johnson. I am Assistant Director of the Environment and Behavior Program at the Center for Science in the Public Interest in Washington, D.C. The Center for Science in the Public Interest is a non-profit organization involved in issues regarding health, nutrition, and the safety of food. We represent a diverse group of over 30,000 nutritionists, educators, physicians, students, housewives, and other consumers. A major concern of many of these individuals is the problem of pesticide residues on food.

Through the Center's Environment and Behavior Program, we are monitoring new research on chemicals that can affect the nervous system and alter an individual's behavior. Much of our work has focused on pesticides, for, in many cases, these substances are specifically formulated to disrupt an organism's nervous system.

I deeply appreciate, Mr. Chairman, the opportunity to comment on the pending legislation before your subcommittee on the Federal Insecticide, Fungicide and Rodenticide Act, and on the question of proper disclosure of health and safety data.

We are well aware of the importance of weighing the costs and benefits of disclosing these data. The public ought to have easy access to information about chemicals that can affect their health. At the same time, corporations should be allowed to protect trade secrets from their competitors. This delicate balancing of interests is embodied under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under the pending legislation before you, this balance is destroyed.

Under FIFRA, manufacturers can protect trade secrets, and any citizen can obtain health and safety data by writing EPA. Under H.R. 5023, manufacturers can still protect their trade secrets, yet citizens can be denied access to important health and safety data (§10(d)(2)(E)).

Arguments against nondisclosure are chiefly supported by a fear that disclosure will diminish research incentives by reducing the profitability of

developing new pesticide formulations. But this fear has not been substantiated by the chemical industry during the eight months of testimony over this bill.

In contrast, the advantages of disclosing health and safety data are clear. Such a move would improve the effectiveness of the Environmental Protection Agency; advance scientific knowledge; and allow citizens to make better informed decisions about the pesticides they use.

IMPROVING ENVIRONMENTAL PROTECTION AGENCY EFFECTIVENESS

Dr. Jack Early, President of the National Agricultural Chemical Association (NACA), testified before this subcommittee that NACA's "companies are not opposed to public oversight of EPA." In fact, Dr. Early continued, "I doubt if any company would be opposed to essentially making the data available to an organization like the Environmental Defense Fund." Dr. Early's connection of public oversight to a need for data is critical. Oversight cannot proceed without free, ready access to health and safety data filed by pesticide registrants. The current FIFRA Section 10 satisfies free, ready access by the public. The pending legislation before you does not.

The proposed amendments muddle the clarity of the current law. What results is a bewildering array of disclosure restrictions creating a bureaucratic maze that would confound even the most skilled rodent. For example, section 10(d)(2)(F) of the amendments states that persons shall not be required to reapply for permission to borrow health and safety data from EPA's reading rooms once permission is initially granted. This clearly suggests a single general application and approval process. However, the same section also notes that the Administrator shall "forward a copy of the application to the business entity originating the information requested [and] provide that business entity ten days to transmit to the Administrator any factual information related to the application..." This provision suggests that applications for reading room privileges are linked to specific requests for data and must be renewed each time a member of the public wishes to use the reading room.

But even more important, the proposed amendments are simply not equitable. For example, the amendments would allow disclosure of health and safety data to selected persons whom EPA deems qualified. There is no review of the EPA Administrator's decision no matter how arbitrary, capricious, or unlawful (§10(d)(2)(E)).

The amendments allow pesticide manufacturers to screen reading room applicants as well. These manufacturers have a vested economic interest in keeping health and safety data out of the hands of the public. The amendments also allow pesticide producers to submit to EPA material critical of any applicant without giving the applicant an opportunity to respond (§10(d)(2)(E)).

The amendments discourage open flow of scientific knowledge to the point of what notes can be taken, with what specificity they can be recorded, and with whom they can be shared (§10(d)(2)(G)).

Finally, the amendments construct a penalty system which places severe penalties on government officials and the public, yet barely slaps the wrists of those corporations who engage in economic espionage. The amendments would set the penalty for illegal disclosure of information by private citizens or government employees at up to \$100,000 and/or imprisonment for up to one year. Corporations found guilty of a similar offense would face no criminal liability and would be eligible for reduced penalties if the Administrator of EPA feels such moderation is appropriate (§14(1)(a)(4)).

EPA faces a difficult task in predicting the likely human and environmental consequences of a pesticide solely on the data submitted by the manufacturer. Data are often scientifically inconclusive, permitting reasonable scientists to arrive at different interpretations. Pesticide producers, because of their financial interest in obtaining EPA approval, often design and report studies in a way that will make their products appear in the most favorable light. We are not cynical enough to believe that chemical manufacturers would knowingly mislead the public, yet history has shown the dangers of not having firm oversight.

The recent indictment of the Industrial Biotech Laboratories for fraudulent pesticide toxicity studies stands as a clear example of the need for such oversight. Another case involving a drug company closely parallels the issue of oversight of pesticide manufacturers and testing laboratories. In 1976, the Food and Drug Administration (FDA) reported to Congress that the G.D. Searle Company had "made a number of decisions which were seemingly calculated to minimize the chances of discovering toxicity and/or to allay FDA concern." The discrepancies in that instance were so severe that the FDA recommended to the Department of Justice that grand jury proceedings be instituted against Searle.

Against these embarrassments, we might paraphrase the moral: "The price of a 'healthful workplace and a safe environment' is eternal vigilance."

Questionable industry interpretations can remain undetected for years. In the instance of the pesticide heptachlor, fifteen years elapsed before the original regulatory decision to accept the manufacturer's interpretation that heptachlor did not cause cancer in rats, and later evaluation of the data, buttressed by independent scientific experimentation, finding strong evidence which indicated that heptachlor was very likely carcinogenic.

Traditionally, the scientific community minimizes these problems and biases by subjecting the results and methods to formal and informal review by other scientists. If, however, the data submitted to agencies may not be disclosed or disclosure is so severely limited as in the pending amendments, the data and test methodology never will enter the normal peer review channels. Cast adrift in scientific isolation, EPA scientists may be more prone to misjudge the accuracy of the data submitted.

We recently investigated one example of agency decision making where we believe such errors in judgment were made. The case involves the pesticide carbaryl. This chemical, manufactured by Union Carbide Corporation under the trade name "Sevin," is one of the largest selling insecticides in America with

sales of an estimated \$20 million annually. Although carbaryl is useful on nearly 100 crops and is effective against a number of insects, tests indicate the product can alter the nervous system and affect behavior. For instance, in one test, the learning ability of laboratory animals was mildly but permanently impaired after ingestion of the chemical. Human experimentation has demonstrated difficulty in sleeping, headaches, and other complaints. Further evidence has linked the pesticide with birth defects, sterility in males, and neurological damage.

These problems prompted EPA to name carbaryl as a candidate for Rebuttable Presumption Against Registration (RPAR) review in 1975. Had carbaryl been funneled into the RPAR review process, its use may have been sharply curtailed or suspended. Yet in December 1980, after five years of gathering health and safety data on carbaryl, EPA suddenly decided to drop the pesticide from pre-RPAR review.

Why was carbaryl dropped? The official explanation for this decision was issued in a decision document which curiously downplayed the importance of scores of tests attesting to the hazards of the pesticide. For example, in reviewing three studies on neurotoxicity, EPA noted that animals exposed to carbaryl consistently developed leg weakness or loss of muscle coordination. Yet without further discussion, EPA concluded that "based on...evidence as summarized above, carbaryl does not pose a neurotoxic hazard."

This curious logic was defended by EPA spokesmen. EPA's project manager for carbaryl, Dr. Jerry Moore, told us that "the weight of the evidence" suggested that the product ought not be reviewed.

Yet CSPI was able to obtain internal EPA memos that paint a picture of agency decision making impeded by the influence of a pesticide manufacturer. These memos, along with off-the-record discussions with EPA scientists, confirm that throughout EPA's five years of investigating the health and safety data on carbaryl, Union Carbide representatives met repeatedly with EPA staffers, often submitting lengthy documentation attesting to the alleged safety of the pesticide.

One former EPA project manager for carbaryl told CSPI, "Union Carbide kept coming to us saying 'We're having problems with our overseas sales,' reminding us that carbaryl had been banned in Egypt just because we had it under consideration for review here. They kept pressing us to make up our minds one way or the other, hopefully in Union Carbide's favor."

This repeated lobbying apparently paid off. EPA decided to cancel its review, despite the strong objections of a senior agency scientist who wrote, in a draft memo obtained by CSPI, that the decision document "does not appear to be justified" by the studies presented. "The data lead the reader in one direction, the conclusions in another." Most startling of all was the revelation that EPA's Office of Pesticide Programs (OPP) bypassed a standard agency procedure of letting other EPA offices review the draft document before making it public. Yet OPP circulated the draft decision document to Union Carbide for comment before it was published! In the words of the memo, "If there was

time for Union Carbide to examine the document, there should have been time for the agency to review it, too."

We believe that the carbaryl case illustrates the risk that EPA runs of becoming captive to a company that Congress has instructed it to regulate. This can happen when an agency's decisions about the importance of health and safety data are made in isolation, outside of the normal peer review channels. Giving everyone open access to these data will allow them to be interpreted by the entire scientific community—not just industry scientists and a handful of agency decision makers. The result will be more impartial decisions.

The House Government Operations Committee recently raised serious questions about a similar example of industry muscle apparently being used to influence EPA's decisions on health and safety data. At issue was the propriety of EPA Deputy Administrator Dr. John Hernandez' meeting with industry representatives during the debate on the widely used chemicals DEHP and formaldehyde. Between June 19 and September 29, 1981, EPA held six meetings with these individuals. Ninety-two persons attended these meetings, yet no consumer, environmental, labor, or public interest groups were in attendance. This lack of regulatory mentality in what can only be characterized as a policy-influencing context raised the serious concern of Members of Congress and may well increase the skepticism with which Americans view their government. EPA should not become captive to the ways a regulated industry views health and safety data.

ADVANCEMENT OF SCIENTIFIC KNOWLEDGE

Not allowing health and safety data to be freely circulated among scientists may mean that EPA scientists will work in a vacuum. If individuals are prohibited from using scientific information, the atmosphere in the agency can be stifled and professional growth of the staff seriously hampered. Again I point to an example from the FDA. Interviews conducted by a public interest group with FDA staff (who are faced with similar disclosure prohibitions as are envisioned in the amendments before you) show that many FDA scientists refuse to discuss their work with outsiders for fear of inadvertently disclosing trade secrets, thereby foreclosing practically all contact with scientists and others in their respective fields.

We ask the subcommittee to consider these points in its final review of the proposed Section 10 amendments. Health and safety data have a scientific value as well as an economic value. Nondisclosure preserves corporate economic value but substantially reduces the scientific value. The scientific value of health and safety studies is seriously discounted when the information is withheld from the scientific community. Congress should be forewarned of the serious adverse consequences when balancing the competing public policy questions.

First, the value of scientific peer review is lost and errors in test methods or data may not be detected. Inability to identify potential dangers because of faulty data may have serious human and environmental consequences.

Second, there may be unnecessary and needless duplication of testing with the attendant waste of scarce scientific resources.

Third, the advancement of scientific knowledge can be hindered by one researcher's lack of access to the experience of another.

To say that these varying concerns are difficult to harmonize is an understatement. There is, of course, value to the information in which companies so diligently invest. Yet, companies are rewarded for this investment by the right and privilege to market pesticides under patent laws and the exclusive use of data requirements already granted under FIFRA and to be increased in the Section 3 amendments before you. Studies show the domestic chemical industry to be highly profitable and highly concentrated.

Protection of the industry from fear of undemonstrated harm is too costly to the public and scientific community.

MORE INFORMED DECISIONS BY CITIZENS ABOUT PESTICIDE USE

I mentioned earlier that Center for Science in the Public Interest represents many thousands of our members and other consumers who are concerned about the safety of the food supply. Some of these persons operate food stores across the country; others are farmers, public health officials, nutritionists, educators, or school cafeteria operators. We recently telephoned a sampling of these individuals to record their reaction to the proposed changes in section 10 of FIFRA.

Many food store owners were worried that the proposed amendments would block the flow of information about pesticides to the public. Some of these owners, like Harrison Drinkwater of Hanover, New Hampshire, try to supply information about pesticides to their customers. Mr. Drinkwater said that his store would be "severely handicapped" by the proposal. As one who has obtained valuable health and safety information on pesticides from EPA's Regional Office in Boston, Mr. Drinkwater fears that these new proposals would hamper the flexibility of the government in responding to citizen requests.

Other food store owners agreed with Mr. Drinkwater's analysis. Mary Theresa Gray, from the New Brighton (Minnesota) Co-op Store, pointed out that the amendments seem contrary to the Reagan Administration's goal of streamlining, rather than building, a bureaucracy. Diana Rainwater from Puget Consumer's Co-op in Seattle said the amendments would construct a system so cumbersome that "only the most diehard consumers would succeed in getting the information they need." This comment was repeated by several respondents. Mark Burkush, assistant Food Services Director for the Manchester, New Hampshire school system, thought the proposals would "intimidate people from seeking information." Jan Kulikowski, nutritional care coordinator for a Jersey City, New Jersey, hospital told us "If I want information about a pesticide, I would like an easy way of obtaining it rather than going through a lot of red tape." Gary Osteraas, a college nutrition teacher from Worcester, Massachusetts, doubted that small farmers and food distributors interested in health and safety data would take the extra step to obtain it that the amendments would require. The hardship and frustration these amendments would pose are perhaps best summed up by Mattie Perelman, a housewife from Katonah, New York, who asked "Who on earth would have the patience?"

These are but a few of the comments that citizens have registered in opposition to H.R. 5203. I submit that this is the very tip of the consumer

opinion iceberg. Citizens throughout the nation value the concept of informed choice. The provisions embodied in the legislation before you today do not do this concept justice.

SUMMARY

The Center for Science in the Public Interest supports the policy contained in FIFRA that data should be made readily available to all members of the public. We oppose the present amendments, which restrict access to data. We believe any revised version of the Act should contain measures other than those in H.R. 5203 to protect the confidentiality of corporate trade secrets.

As an addendum, I would like to submit an open letter to Congressman Brown and Senator Lugar from other concerned scientists who attended the American Association for the Advancement of Science convention in this city last month. The proposed amendments to Section 10 were then available for analysis. Over one hundred scientists and others from varying disciplines, institutions and sectors of the economy asked this subcommittee not to restrict access to data. I would like to ask that the letter and the names of persons signing be inserted into the record.

Thank you for the opportunity to appear before you this morning.

TESTIMONY OF
JACQUELINE M. WARREN
ON BEHALF OF
NATURAL RESOURCES DEFENSE COUNCIL
ENVIRONMENTAL/ DEFENSE FUND

Summary

After reviewing H.R.5203, the Natural Resources Defense Council (NRDC) and the Environmental Defense Fund (EDF):

- (1) strongly oppose the proposed amendments to §10;
- (2) urge the Subcommittee to restore to environmental, labor, and consumer organizations, and to all members of the public, the right to challenge EPA's pesticide regulatory decisions in adjudicatory hearings before the Agency under §6(b) of FIFRA;
- (3) oppose the proposed amendments to §24 for the reasons stated by the State of California in their testimony; and
- (4) strongly support the following proposed additions to the Act (by order of section):
 - (a) section 3(c)(8)(D) - provision of direct appellate review of decisions not to cancel or suspend the registration or to restrict the classification of a pesticide following interim administrative review;
 - (b) section 3(d)(1)(C)(ii) - specific inclusion of groundwater protection considerations in imposing restrictions on pesticide use;
 - (c) section 16(e) - addition of a private right of action for persons aggrieved by misuse of a pesticide; and
 - (d) section 25(e) - provision of a deadline for EPA to adopt guidelines establishing safe use of pesticides and safe working conditions for farm workers, pest control applicators, and other persons handling, storing, or applying pesticides or working and living in and around pesticide treated areas.

I. Section 10: Restrictions on Public Disclosure of Health and Safety Data Supporting Pesticide Registrations

NRDC and EDF remain strongly opposed to any change in §10 which will restrict public access to health and safety data supporting pesticide registrations, for the reasons stated in our earlier testimony. We believe that the proposed language poses several serious obstacles to full public disclosure of such data. First, it remains unclear whether EPA will be able to provide adequate funding to staff and operate reading rooms at EPA headquarters and in each of the ten regional offices. In our view, such funding is unlikely in the current budget cutting climate.

Even if adequate funds were to be available, the operation of the reading rooms and the gaining of access to them remains problematical. For example, it is unclear whether application for access to a reading room must be made in advance of actually entering the reading room. Proposed §10(d)(B) states that "any person described in subparagraph (A) who wishes to make use of the reading room for any purpose" must state in writing their affiliation and a description of the data sought as well as a declaration that the person will not misuse the information by disclosing it to persons not authorized to receive it. In addition, such applicants must comply with the rules and procedures established by the Administrator. This language suggests that a person cannot simply appear at a reading room

and expect immediate entry. Thus, there is a prospect of serious inconvenience to members of the public who travel to headquarters or a regional office to use the reading room.

A second problem is posed by the strict limitations on what material in the reading room may be copied. Under present law, complete health and safety studies are fully available to the public. The proposed amendments would limit free copying merely to charts, graphs and tables containing statistical data. While earlier drafts of the amendments also permitted copying of conclusions and executive summaries, this is now prohibited. These limitations greatly diminish the utility of the data.

Although provisions for removing complete studies is made in paragraphs (D) and (E) of proposed §10(d)(2), the use of those data after removing them from the reading rooms is also strictly circumscribed. From the very first point of attempting to remove data from the reading room, the proposed amendments establish serious difficulties and contain ambiguities which are certain to have a chilling effect on parties desiring to make use of the data. For example, no criteria for the granting of applications for removal of data are contained in the statute. Even the applicable time frames appear confused and contradictory. In §10(c), entitled "Disputes", the Administrator is directed not to make available for inspection any data about which the confidentiality is disputed until 30 days after receipt by the owner of the data of the Agency's intention to disclose it.

Section 10(d)(1) provides that before disclosing any information in response to a request, the Administrator must provide up to 60 days for the owner of the data to identify any portions that it claims are exempt from disclosure, and to substantiate such claims. At the same time §10(a) provides that such identifications and substantiations must be made when the data are originally submitted. Later on, §10(d)(2)(E) provides that the Administrator must grant permission to remove data from a reading room not more than 30 days after the application has been received unless permission to withdraw the data is denied. In light of these many different time frames, it is unclear precisely how expeditiously members of the public will be able to remove from the reading room studies now fully available under current law.

Not only are there no criteria included to govern the Administrator's decisions with respect to requests to remove data from the reading room, but the proposed amendments specify that such decisions "shall be final and not subject to judicial review." Criteria governing such decisions should be limited exclusively to considerations of commercial disadvantage, or the public will be entirely unprotected against arbitrary and capricious denials.

Perhaps one of the most serious problems with the proposed changes to §10 involves the penalties for improper disclosure

of information taken out of the reading room. Proposed §(d)(2)(G) provides that documents containing information removed from the reading room "shall not be disclosed or made available in any manner by the borrower to any other person." That section also contains a blanket prohibition on reproduction "in any manner of any material borrowed from the reading room." The only material that may be freely used in administrative, judicial, legislative or other proceedings, or utilized in any other manner are the charts, graphs, statistical tables and notes taken from the available studies. It is not clear whether executive summaries and conclusions may be copied and quoted verbatim. Moreover, the penalty for violating the somewhat ambiguous and contradictory provisions of this paragraph is the debarring from all further access to the reading rooms of the person involved and "any other person upon whose behalf he or she was acting." In our view, the severity of this sanction, and the apparently blanket coverage of the prohibition on disclosure to any person "in any manner," create insurmountable obstacles to meaningful public access to and use of the health and safety data supporting pesticide registrations.

Perhaps in recognition of the fact that complete studies must be available for use in litigation proceedings, §10(f), entitled Disclosure to Pesticide Producers, provides that

complete studies may be used in administrative adjudicatory hearings or court litigation, "if the party's access to the data is found to be necessary in order to allow the party to participate fully in the hearing or litigation." How, when, or by whom such determination of necessity is to be made is not explained.

As stated in our earlier testimony, the 1978 amendment to §10 was the product of a carefully weighted effort to balance the concerns of both the manufacturers and the public regarding data disclosure. It is apparent from the debates and the committee reports on the 1978 amendments that one of the principal objectives in enacting the provision for disclosure of health and safety data underlying pesticide registrations was protection of public health. In providing for public disclosure of such data, Congress was seeking to remedy the well documented shortcomings in EPA's on-going attempt to assess the validity of those data. The disclosure provisions constitute Congress' recognition that the public has a right to see such health and safety data, and an important role to play in evaluating and ensuring that EPA's pesticide regulatory and registration decisions are made on a sound scientific basis. Given current and projected cutbacks in EPA manpower and resources, this public input is more important and necessary than ever before. For this reason we strongly oppose the enactment of the §10 amendments contained in H.R.5203.

The agricultural chemicals industry has not presented a persuasive case for making the drastic change in §10 embodied in these amendments. Environmental, labor, and other organizations representing the public interest in free access to such data have remained unanimous in their strong opposition to the enactment of these amendments. We therefore urge the Subcommittee to reject the proposed amendments to §10.

II. Restoring the Standing of Members of the Public to Challenge Pesticide Regulatory Decisions in Adjudicatory Hearings at EPA

Since the proposed amendments already contain changes to §6(b) of FIFRA, NRDC and EDF urge the Subcommittee to enlarge the §6(b) amendments by restoring the standing of environmentalists, labor unions, consumers and other members of the public to challenge EPA's pesticide regulatory decisions in hearings before the Agency. As presently phrased, §6(b) provides that "a person adversely affected by the notice" of cancellation can request a hearing at EPA. That language should cover all persons "adversely affected," and from 1972 to 1979 was interpreted by EPA as doing just that. In 1979, however, EPA reinterpreted the language of §6(b) to mean that only registrants and users of pesticides, i.e., those with an economic interest in the continued registration of a pesticide, can be "adversely affected" by a notice of intent to cancel. As a result, only those persons who believe that a proposed regulatory action goes too far (typically, registrants and users) are entitled to a hearing to challenge

EPA's action. Those who believe that the action does not go far enough, or is otherwise inadequately protective of health or the environment, (typically environmental groups, farmworker organizations, and consumer organizations) are not entitled to a hearing. By re-interpreting the words "adversely affected", EPA has excluded the general public from meaningful participation in pesticide regulatory proceedings. The Agency's position, which represents a complete reversal of its position on this issue for the past 10 years, has been affirmed by the U.S. Court of Appeals. Environmental Defense Fund v. Costle, No. 79-1971 (D.C. Cir. July 17, 1980).

In our view, it is unfair to exclude members of the public from challenging the adequacy of pesticide regulatory decisions in hearings before the Agency, while guaranteeing the right of the pesticide producer and user groups to challenge the stringency of such decisions. We do not believe that Congress meant to create such a discriminatory procedure when the words "a person adversely affected by the notice" were included in §6(b) in 1972. We therefore strongly urge Congress to correct this inequity and to restore the public's ability to request and participate in pesticide regulatory hearings at EPA. Members of the public had this right from 1972 to 1979. They do not have it now. If the commitment of this Subcommittee, and indeed of the entire Congress, to public involvement in and oversight of EPA's pesticide regulatory decisions is to be more than lip

service, the right of members of the public to standing in EPA's pesticide hearings must be restored.

The standing issue is not hopelessly complex or technical; on the contrary, it is a simple question of fairness. To assure that members of the public are once again included in the review and decisionmaking aspects of the pesticide re-registration process, we recommended statutory language to clarify that the right to hearings in §6(b) includes all persons adversely affected by the notice. A one-word change in §6(b), accompanied by a clear statement in the committee report of intent to include environmental, labor and consumer groups, and all other citizens who believe themselves to be adversely affected by a notice, could rectify this inequity. If such a change were made, §6 would then appear as follows:

Sec. 6. Administrative Review; suspension.

(b) Cancellation and Change in Classification.--

The proposed action shall become final and effective at the end of 30 days upon receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time... (ii) a request for a hearing is made by any person adversely affected by the notice.

While the provision of direct appellate review of EPA's pesticide regulatory decisions following the interim administrative review under §3(c)(8)(D) represents a necessary and

appropriate amendment to §3, since there will be a rulemaking record already available for review by the Court of Appeals, it is not a substitute for standing under §6(b). Section 3(c)(8)(D) addresses judicial review--it does not apply to agency hearings. We therefore urge the Subcommittee to adopt the simple one-word change in §6(b) that will restore the balance and enable the public to participate once again in hearings before EPA involving the adequacy of pesticide regulatory decisions.

Conclusion

As set forth in the summary on the first page of this testimony, NRDC and EDF do support a number of the amendments contained in H.R.5203. We recommend that the Subcommittee adopt those amendments as set forth in the bill. In addition, we hope that the Subcommittee will adopt the amendment we have suggested concerning our hearing rights under §6(b). Most importantly, we urge the Subcommittee to reject the proposed amendments to §§10 and 24.

STATEMENT OF THOMAS O. MCGARITY

PROFESSOR OF LAW, UNIVERSITY OF TEXAS SCHOOL OF LAW

I am pleased to be here today to speak once again to the issue of the trade secret status of health and safety data under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 135 et seq. (FIFRA). I will address in particular draft amendments to Section 10 of the Act, and the potential for costly and time-consuming litigation that those amendments, if enacted, would present.

The merits of public disclosure of pesticide health and safety testing data have been debated at length before this committee. My previous testimony to the Subcommittee detailed the advantages of public disclosure. Given the current statutory regime, there is only one conceivable disadvantage--viz. the possibility that data disclosed to the public will be used by competitors in foreign countries to register competing products in those markets. Nowhere in the hearings thus far conducted by this Subcommittee have the pesticide companies or their representatives seriously attempted to validate their claim that the possible loss of their monopolies in foreign markets will cause them to reduce their research and development efforts in the United States.

The current FIFRA seriously penalizes anyone who knowingly uses data procured from EPA to aid a company in entering a foreign market. The proposed Amendments to Section 10 would greatly hinder citizen access to health and safety data without adding any realistic additional protection beyond a ten-fold greater potential fine. A serious foreign competitor, who is not

opposed to violating the law, will obtain its data under either approach. The theory of the proposed amendment appears to be that limiting access to the data to those citizens with strong writing hands who are willing to drive hundreds of miles will somehow reduce the flow of information to foreign markets. I suspect that the Bill if enacted will not accomplish this purpose; rather, I suspect that it will operate in practice only to restrict the flow of information to the American public.

I. Restrictions on Citizen Access to Information.

The proposed Amendments to Section 10 would make it extremely inconvenient and somewhat risky for an ordinary citizen^{*/} to obtain access to health and safety data. The citizen must first travel to an EPA Regional Office. In many cases this can entail a trip of a thousand miles or more.^{**/} Once the citizen arrives at the Regional Office, he must fill out a form and sign a statement that he will not cause the information he seeks to be disclosed to another pesticide company.

The citizen then finds that unless he fits within a rather poorly defined category of privileged persons, he may not "check out" the data and return it later. Even if he falls

^{*/} In using the term "ordinary citizen" I mean to include scientists, homeowners, farmers, physicians, lawyers for persons injured by pesticides, and any other person who has no competitive interest in studying health and safety data.

^{**/} For example, air fare from El Paso, Texas to Dallas, Texas (the location of the EPA Regional Office for Texas) is approximately \$120.00 round trip as of February 1, 1982

within the privileged category, he may not make use of modern xerographic technologies, except to reproduce certain charts and graphs containing "statistical" information. All other information must be reduced to his personal handwriting, or perhaps read into a tape recorder. The Amendments make no provision for viewing microscopic slides (the ultimate "raw data" underlying animal toxicity studies); nor does the statute mention the availability of the agency's correspondence files, which can often be more revealing than the studies themselves. Presumably the agency regulations that the Amendments envision will address these later problems. But given its current reduced staff and restricted resources, it may take the agency years to promulgate such regulations.

The penalties for revealing health and safety data to unauthorized persons are so stringent that the ordinary citizen may not have the courage to risk becoming the recipient of an unfounded charge that he disclosed protected data to unauthorized personnel. Once having obtained access to the data, the citizen must live with the knowledge that if a foreign competitor ever obtains access to the data through any source other than the data producer, the citizen will be a prime suspect in the ensuing investigation. This knowledge is likely to have a chilling effect on persons who might otherwise desire to study the data. It will likewise have a chilling effect upon EPA employees who must make the threshold determination whether or not to allow a citizen to have access to the data

in the reading room. Under the perceived threat of civil and criminal penalties, EPA employees will undoubtedly resolve all doubts against disclosure, thus depriving legitimate observers of their right to study the data. Significantly, while the proposed Amendments provide numerous protections to data producers, they do not explicitly provide an expedited avenue of appeal for those who have unlawfully been deprived of their right to study health and safety data. Moreover, the Amendments provide no explicit time limit within which EPA must decide whether to allow a citizen into the reading room. Hence, a citizen may travel hundreds of miles to an EPA Regional Office, fill out his application form, and then discover that EPA must "screen" him for acceptability, a process that could go on for weeks or months.

II. Litigation as an Alternative to Disclosure.

In the past, pesticide data producers have effectively used litigation as a tool to prevent disclosure of health and safety data to the public. During the early and middle 1970s, data producers argued in several courts that FIFRA did not authorize EPA to release health and safety data. In an effort to put this litigation to rest, so that EPA could get to the business of registering "me-too" producers (with statutory compensation being paid to the original data producers), EPA suggested FIFRA amendments to Congress which would exclude health and safety data from the definition of "trade secret" in Section 10. Congress enacted this Amendment in 1978.

The data producers immediately returned to court to challenge the constitutionality of the 1978 Amendments. Responding to claims that disclosure of the data would work irreparable harm, district courts across the country, often with EPA's acquiescence, issued preliminary injunctions prohibiting the agency from releasing the data until rulings could be made on the merits of the constitutional claims. These pending cases have effectively tied up health and safety data for almost four years. Last June one of the many injunctions finally was lifted after the Supreme Court denied certiorari in an appeal from the Second Circuit's decision that the 1978 Amendments were indeed constitutional. Union Carbide Agricultural Products Co. v. Costle, 15 ERC 1113 (2d Cir. 1980), cert denied, ____ U.S. ____, 15 ERC 1758 (1981). However, EPA has still to release any of the data involved in that case. Indeed, EPA is seriously entertaining a petition from several chemical companies urging it to refuse to release any data until Congress can be persuaded to amend the statute once again to preclude release. EPA acquiescence in this request would be wholly unlawful. Indeed, EPA is currently in violation of the Freedom of Information Act, because it has refused to make requested studies available to data requestors, including lawyers representing farmworkers who have been injured through the misuse of pesticides, until this moment.

This brief history should demonstrate that pesticide data producers stand ready to litigate virtually every nuance of a statute or an amendment--litigation will put off the final

date of mandatory disclosure. The proposed amendments contain sufficient ambiguities to sustain another four years worth of litigation. To illustrate the opportunities for delay that the Bill, if enacted, would provide to a determined data submitter, I would like to suggest for you the hypothetical case of the editor of the newsletter for a national environmental group. (The hypothetical is equally applicable for the doctor who would like to use pesticide health and safety data for an article to be published in a medical journal). The editor, who also has a background in toxicology, would like to publish a short article on the health effects of a commonly used household pesticide.

Since the health and safety data are not likely to be located in EPA's San Francisco Regional Office, she calls ahead to that office to request that the data be transferred from Headquarters in Washington, D.C. to that office. The agency locates the data and discovers that they have never before been disclosed to the public. Under Section 10(d)(1) of the amendments the agency must therefore give the data submitter sixty days to identify portions of the study that it considers to be trade secret. The data submitter responds on the sixtieth day that all of the data are trade secret, or, perhaps more forthrightly, it claims that the trade secret aspects of the data are so inextricably intermingled with the non-trade secret aspects that disclosure of any but the most unrevealing passages of the data are protected by Section 10(b) and Section 10(d)(1)

(A) (B) & (C).

If the Administrator finds that the data submitter has reasonably substantiated its claim, that is apparently the end of the matter, because Section 10(c) only gives a pesticide applicant or registrant the right to challenge the Administrator's conclusion.^{*/} If, on the other hand, the Administrator rejects the data submitter's confidentiality claims, the data submitter, under Section 10(c), must be given an additional thirty days to file an action for a declaratory judgment in a federal district court. The federal district judge will almost certainly issue a preliminary injunction pending a decision on the merits and put the case on the docket for argument sometime in the next few months. Eight months later, the court rules in favor of the editor and the matter is appealed to a circuit court of appeals. A stay is issued pending appeal and the data are still not released. Finally after another fifteen months the circuit court of appeals agrees with the district court that the data may be disclosed. The data producer applies

^{*/} The editor, or her lawyer, could argue that the Administrator's refusal to disclose the data is a "final Agency action not committed to Agency discretion by law," and therefore reviewable in Federal District Court under Section 16 of FIFRA. The question then would be whether this action was committed to agency discretion by law. Otherwise, the editor might sue the Administrator under the Freedom of Information Act, 5 U.S.C. § 552 et. seq. The point I mean to make here is that the proposed amendment to Section 10(c) is one-sided. It should at the very least provide for review of agency refusals to disclose information in the same way that it provides for review of agency decision to disclose data.

to the Supreme Court for a writ of certiorari but that is denied five months later, and the injunction is finally lifted. It is now approximately thirty-one months after the editor has requested the data. However, we now have a definitive interpretation of the statute from one circuit court of appeals. Since other circuit courts of appeal are not bound by this determination, future requests for data on different pesticides may consume additional years.

Our editor is now notified that the data that she has requested awaits her at the San Francisco Regional Office. She flies from her home in Hawaii to San Francisco and presents herself to the EPA employee in charge of the reading room. She discovers that a representative of the data producer has been anxiously awaiting her arrival. Before the editor can be seated in the reading room, the representative objects that she is an "employee or agent of a person engaged in, or which intends to engage in, the production or registration of pesticides," or, at the very least, a "person who intends to deliver data . . . to an employee or agent of any business engaged in the production or registration of pesticides."

The editor will, of course, deny that she is an agent of a person engaged in the production of pesticides, but is that denial enough? Perhaps the editor is really a secret agent for another pesticide producer. Is the registrant entitled to a hearing on that issue before the editor may have access to the reading room? The data producer may insist that the editor

be denied entrance until the validity of her denial is established in a federal district court. Will the EPA employee in charge of the reading room, who may be fined up to \$100,000, have the courage to ignore the data submitter's request? Probably not.

If the editor would like to "check out" the data to examine it in a more convenient location or perhaps after business hours, she discovers that she has another 30-day wait while the data submitter argues, pursuant to Section 10(d)(1)(E), that she is not a medical practitioner, health and safety professional or "any other individual or organization not otherwise restricted from access to the reading room." The Administrator's decision on this matter is final and not subject to judicial review.

Assuming that the editor decides to look at the documents in the reading room, she begins to take notes, being careful not to compile a verbatim transcript of the entire study.*/ She does, however, want to copy verbatim the tables containing the pathologists slide-by-slide diagnoses. She would like to xerox these charts, which go on for approximately 100 pages. The data submitter, however, objects on the ground that these charts do not contain "statistical" data; they contain only raw data that have not been subjected to statistical analysis at this point in the study. The timid EPA employee agrees and

*/ I will not discuss here the litigation over whether or not she may use a dictaphone to aid her in her note-taking.

tells the editor that if she wants to perform an independent statistical analysis of the tables, she will have to do that analysis in the reading room.

If the editor wanted to have an independent pathologist examine the slides taken from the animal tissue, she would have an even more difficult time, because the slides are rarely in EPA's possession. The proposed Amendments are silent on whether EPA must make these slides available to independent pathologists, and if so, whether EPA must provide a microscope in the reading room with which to examine the slides. This is not an insignificant issue. Critical re-evaluation of the slides supporting several important pesticides by an independent pathologist in 1976 revealed great disagreements with the original diagnoses. See Staff of Subcommittee on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, 94th Cong. 2d Sess., The Environmental Protection Agency and The Regulation of Pesticides (Comm. Print 1976).

The foregoing hypothetical example should illustrate some of the difficulties that the agency will face in administering the proposed Amendments. These difficulties will add to the cost of the "reading room" program. In a time when budget cuts have rendered EPA largely incapable of performing its statutory duties relating to the protection of the environment, it seems unwise to add to those duties a complicated and expensive program for protecting data. The pesticide producers, who are generally great proponents of cost-benefit analysis, have not demonstrated that the benefits of this proposed new program outweigh its costs.

National Coalition Against the Misuse of Pesticides

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AN ANALYSIS OF H.R. 5203 AS IT PROPOSES TO AMEND FIFRA SECTIONS 10 AND 24

I. Introduction

H.R. 5203 amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This analysis examines changes in two key sections of the Act. Section 10 of the Act governs the disclosure to the public of data submitted by pesticide companies to the EPA. Under the Current Act, trade secrets are not disclosed to the public, but pesticide health and safety studies are not trade secrets, and must be freely disclosed. H.R. 5203 amends the Act to place severe restrictions on the disclosure and use of health and safety studies. Section 24 of the Act governs the state and federal relationship over control of pesticides. Under the current Act, states have broad authority over the sale and use of pesticides within their borders, except for labeling and packaging, which is federally controlled for uniformity. H.R. 5203 amends the Act to restrict states authority over pesticides, especially in the area of data-gathering authority.

II. Analysis of H.R. 5203 as it Proposes to Amend FIFRA Section 1 (Public Disclosure of Pesticide Health and Safety Data).

The provisions in H.R. 5203 with respect to Section 10 of FIFRA are seriously deficient. The problems can be divided into

two groups: (1) conceptual defects, and (2, drafting errors and inconsistencies. This analysis notes some, but not all, of these deficiencies. It concludes that no change in the present law is much preferable to the amendments in H.R. 5203.

A. The Current Act

The current Section 10 of FIFRA -- as distinct from the proposed amendments -- is a straight-forward reconciliation of two conflicting public policies. The current Act attempts to protect company trade secrets and, at the same time, insure that health and safety data on toxic chemicals is available to the public and independent scientists. The mechanism of reconciliation is simple. In order to register a pesticide for sale and distribution, the manufacturer of the chemical must submit testing and formulation data to the Environmental Protection Agency (EPA) for review. When a company submits its data, it may designate which items constitute non-disclosable trade secrets. Under Section 10(d) of the current Act, the company has broad authority to claim trade secret status for commercial and financial information including manufacturing processes, and identity of inert ingredients. This material remains protected.

The public may have access to non-trade secret data on the health and safety hazards, or data on effect on wildlife by submitting proper requests to the EPA under the Freedom of Information Act (FOIA). Designated trade secret data remains

undisclosed; non-trade secret information is provided to requesters at their expense. If any party wishes to challenge the EPA's release of data, they may petition the United States District Court for review of the agency's actions. Thus, if a company feels disclosure will unduly compromise their commercial position, they may move to block release. Similarly, if members of the public feel the EPA has been unduly restrictive in its release, they too may seek judicial review.

The current system adequately protects the competitive advantage of pesticide manufacturers and, at the same time, insures public review of data which is critical to the continued health of the American public, and protection of the environment.^{1/} Most importantly, the system is conceptually simple and workable. It does not require substantial funding or substantial bureaucratic growth.

B. The Proposed Amendments

The proposed amendments destroy the clarity and even-handed nature of the current law. At the urging of the chemical industry,

^{1/} Certain chemical industry spokespersons have argued that the current Act fails to protect them adequately from competitors. They have, however produced no evidence to confirm the argument. Indeed, whatever evidence there is seems to point in the other direction. In addition to the trade secret protection of FIFRA, pesticide producers have substantial patent protections against domestic competitors. In those foreign markets where no patent protection exists, the Food and Drug Administration has concluded that release of drug data would have only a very marginal impact on United States producers. See U.S.F.D.A. Supplementary Analyses of the Impact of Provision in S. 2755 Regarding Disclosure of Safety and Effectiveness Data on Foreign Markets of U.S. Multinational Firms. Similarly low impact would in all probability also characterize the release of pesticide data.

the amendments severely restrict access to non-trade secret health and safety data. Under the proposed amendments, cancer incidence studies, genetic defect data, exposure incidence data, medical treatment descriptions and a host of other public health material will be kept from open and free discourse by a bewildering and expensive array of disclosure restrictions.

Some examples:

1. Under H.R. 5203, disclosure of non-trade secret data will be controlled by a network of "reading rooms" staffed and operated by the EPA (H.R. 5203, p. 35). The expense of additional staff, data transmission systems, additional record-keeping, applicant screening, and overhead has not been considered, much less estimated, by the drafters of the amendments. At a time when EPA anticipates severe budget cuts, the proposals are, at best, ill considered.

2. H.R. 5203 allows disclosure of non-trade secret data only to selected persons whom the EPA deems qualified to see the data (H.R. 5203, p. 38). There is no review whatsoever from an EPA Administrator's decision to deny access to members of the public. No matter how arbitrary or capricious or unlawful, the proposed amendments insulate the Administrator from challenge (H.R. 5203, p. 39).

3. The amendments provide that reading room applicants will be screened by the industry as well as EPA. The bill allows chemical companies to submit material critical of any person who

seeks access to the reading rooms. Remarkably enough, however, the bill provides no opportunity whatsoever for the applicant to respond to or even be informed of material submitted by a chemical company to block access to the reading room, (H.R. 5203, pp. 38-39). This unfortunate bias further underscores the need for judicial review of the whole reading room application process.

4. Once access to a reading room is granted, the proposed amendments actively discourage the open use and discussion of health and safety data among members of the public and the independent scientific community. They restrict what material can be photocopied and disseminated (H.R. 5203, pp. 39-40). Such restrictions on disclosable non-trade secret data represent a dramatic reversal of the spirit of open and free discourse which science and academia have struggled to develop.

5. The proposed amendments contain no time limits within which the EPA must provide data to approved reading room applicants. The agency may delay for months or otherwise refuse to act without challenge. Current disclosure is governed by the time limits of FOIA and requires EPA to process requests in an expeditious manner. The proposed amendments eliminate such checks on agency behavior.

6. The proposed amendments are poorly crafted. The result is a vague and often inconsistent statute. It is not at all

certain, for example, whether members of the public must obtain reading room approval for each data request, or whether a single general approval is contemplated. Section 10d(2)(F) states that persons shall not be required to reapply for permission to borrow from the reading room, (H.R. 5203, p. 39). This clearly suggests a single general application and approval process. However, the same section also notes that the Administrator shall "forward a copy of the application to the business entity originating the information requested [and] provide that business entity ten days to transmit to the Administrator any factual information related to the application..." (Id.) This provision suggests that applications for reading room privileges are linked to specific data requests and must be renewed each time a member of the public wishes to use the reading room. Nowhere in the proposed amendments is there clarifying language.

7. Finally, the proposed amendments construct a penalty system of questionable impact. For government officials or members of the public, the penalties for inappropriate release of data are severe. They include substantial fines and imprisonment. On the other hand, penalties against chemical companies who steal data are much lighter. Such companies face no criminal liability. They are eligible for reduction in any and all penalties if the Administrator feels such moderation appropriate. Indeed, simple warning letters to companies that engage in commercial espionage are contemplated (H.R. 5203, p. 44). This is

hardly the stuff of which trade secret protection is made. The probable impact of these provisions is to deter the release and discussion of any data -- including disclosable health and safety data -- by EPA officials or interested members of the public, while providing no increased deterrence against commercial espionage, which is the purpose of trade secret doctrine in the first place.

C. Conclusion

The Section 10 amendments represent a substantial retreat from the principle of open discussion of health and safety data. Pesticides are highly useful, but dangerous, toxic chemicals. Public acceptance of pesticide use must be founded on confidence in the regulatory program. Severe restrictions on disclosure of health and safety tests can only result in greater fear and distrust.

If the purpose of these Section 10 amendments is to protect pesticide companies from ruthless competitors, they fail because they do not protect trade secrets any more than the current Act. A system of severe penalties in the United States for trade secret thieves could be drafted, but it hasn't been drafted here.

If the purpose of these Section 10 amendments is to limit, as much as possible, public and independent scientific review of pesticide health and safety studies, they succeed. The cost of such success in tolerance of pesticide use would remain to be answered.

III. Analysis of H.R. 5203 as it Proposes to Amend FIFRA
Section 24 (State Authority).

A. Overview.

1. Overview: The Current Act.

State authority to regulate the sale and use of pesticides is within the traditional police power of the states under the U.S. Constitution. In 1972 Congress wrote the basic structure of the federal pesticide law, FIFRA, as it appears today. The issue of state authority was settled at that time in response to pesticide industry demands for uniformity and state demands to protect historic state police power. (Some states had developed full scale pesticide regulatory programs well in advance of the federal program.) The 1972 compromise was simple, clear, and has worked effectively since that time. It is contained in FIFRA Section 24.

Section 24 in current law authorizes the states to regulate the sale and use of pesticides within their borders with two basic limitations: (1) states cannot be less restrictive than the federal government (e.g. cannot approve a federally banned pesticide), and (2) states cannot change labeling or packaging, which are determined federally. These provisions allow a national uniform labeling and packaging system, assure minimum national safety standards, and preserve the historic authority of states.

2. Overview: Proposed Amendment.

H.R. 5203 attacks a state's authority to regulate pesticides by attacking the state's ability to regulate pesticides; that is, limiting the state's power to obtain information with which to regulate. H.R. 5203 sets up a complicated, expensive, federal/state bureaucracy designed to have the federal government review (and possibly veto) a state's requests to pesticide companies for information about the pesticides which the companies desire to sell in the state. Under current and historic law, states, which have the power to regulate pesticide use, may ask the selling company for data on safety, or effectiveness of its pesticides. H.R. 5203 sets up a series of bureaucratic hurdles that must be cleared by a state, before it can ask for such information.

The ability to obtain data is inherent in the ability to regulate. H.R. 5203 runs contrary to this basic governmental concept, and should not be approved.

B. Detailed Analysis of H.R. 5203 Section 24 Amendments.

1. Section 24(a) remains unchanged. It provides that a state may regulate the sale or use of a pesticide, (and establishes the federal minimum standard).

2. New Subsections are added to §24(a) which limit a state's authority to require data from a pesticide company which

desires to sell a pesticide in the state.^{2/} The basic scheme divides a state's data requests into three categories:

- a. Data previously submitted to the federal government;
- b. Additional data which relates to a "special local concern" by the state;
- c. Additional data which does not relate to a "special local concern" by the state.

3. Category "A": Data Previously Submitted. (Page 49, lines 13-22.)

If a state asks for a copy of data previously submitted by a chemical company to the EPA, the request falls in this category. This subsection authorizes the company to refuse the state's request for a copy of the study. The state must then obtain the copy from the EPA. (The state may go directly to the EPA.)

Analysis: This subsection will result in a significant change in current practice at taxpayers' expense. If a company

^{2/} When a state asks for data from a pesticide company about a pesticide, the data include:

- a. Animal tests on the acute and chronic toxicity of the pesticide. For example, does the pesticide cause cancer, birth defects, nerve damage, genetic mutations, severe acute injury, etc.?
- b. Environmental fate and chemistry tests. What becomes of the pesticide after it is used in the environment?
- c. Efficacy tests. Does it work well on the target pests and crops?

provides the data directly to a state, the data is not subject to Section 10 disclosure controls. Therefore, companies will always refuse to provide the data because: (a) the costs of reproduction and handling are thereby shifted to the federal government, (b) Section 10 restrictions apply, and (c) considerable delays in data transmission by the EPA can be expected, thus discouraging such requests. Under current law, states may simply require companies to provide them a copy.

4. Categories B and C "Additional Data." (Pages 49-52.)

Whenever a state asks for data which has not been previously filed with the EPA, it must either fall in category "B", special local concern, or "C", other. These categories are broader than they may at first appear, because of the massive federal "data gap."

Analysis: According to the General Accounting Office, the key health and safety data for most pesticides now in use have never been submitted to the EPA. This data gap exists because requirements for cancer, birth defect, and genetic mutation data were imposed after the federal government had already registered most pesticides now in use. Such pesticides were grandfathered in. Therefore, when a state asks a company for a cancer test for a pesticide, the state's request may fall in category "C", even though the EPA now requires such a test for all new pesticides. As can be seen below, the classification of each state data request is crucial.

5. Category "B": Special Local Concerns. (Page 49, line 23 through p. 51, line 20.)

This section authorizes a state to obtain additional data relating to special local concerns on safety and efficacy in the state.

H.R. 5203 provides a right to pesticide companies to sue a state in Federal District Court over the state's determination that a data request relates to special local concerns, but

prohibits EPA review of a state's determination of this issue. (Page 50, line 19.) While not defined in the bill, the implication is that the concern is one relatively unique "in the state." Thus, a data request for residue hazards on a crop unique to California or Maine would clearly be in this category. However, California's requests for "metabolic pathway" data on rat poisons and "indoor exposure data" for home use pesticides are not unique to that state. Thus, such requests would fall under category "C".

Assuming that a data request is under category "B" and is either unchallenged, or upheld as belonging in category "B" by the Court, the following rules apply:

a. If the state request is for (i) a restricted use pesticide, or (ii) a general use pesticide used on a commercial food, feed, fiber or grain crop, the state request is final, and the company must provide the data.

b. If the state request is for other general use pesticides, the company may appeal the request to the Administrator of EPA. The Administrator may then:

(i) "Nationalize" the request by reissuing it under 3(c)(2)(B) of FIFRA. (The company then submits the data to EPA, instead of the state), or

(ii) Overrule or modify the request on grounds that the state's data request is (a) arbitrary or capricious, or (b) is duplicative of an existing data source which is

comparable in the opinion of the Administrator. (Pages 50-51, lines 15-25, 1-3.)

The state may obtain judicial review if the Administrator vetoes or modifies its request. The company may obtain judicial review of the state's request, before or after the Administrator's review, and the Administrator is barred from participating in the suit. (Page 51, lines 8-16.)

Analysis: The hidden policy here is the distinction between agricultural and non-agricultural pesticides. State authority is most vulnerable to restriction for home and garden use pesticides. They are responsible for the most recorded poisonings, especially of children. Some states, including California, have been critical of EPA's poor record in regulating home use poisons. The "sponsor" of Section 24 amendments is the Chemical Specialty Manufacturers Association, which represents companies specializing in home use products.

6. 'Category "C": Non-special Local Concern, State Data Requests. (Pages 51-52.)

Category "C" data requests must be sent by the state to both the company and the Administrator. The following then occurs:

a. If the Administrator does not act within 60 days, the request is approved;

b. The Administrator may "nationalize" the request by adopting it as an EPA request under 3(c)(2)(B);

c. The Administrator may veto the request on grounds that it is (i) arbitrary or capricious or (ii) there is no reasonable basis for the state to use the data.

All judicial review of the Administrator's actions is barred.

Analysis: Most state data requests will fall under this category. This category requires the request to be sent to (and presumably reviewed by) EPA. Thus a duplicative system is established. Secondly, it grants broad authority for EPA veto, with no judicial recourse for the state.

7. In addition to the restrictions on state data gathering, H.R. 5203 amends Section 24 to mandate time limits for state review of pesticide applications.

The applicable time limits for state review depends on whether the state has successfully issued a "special local concern" data request. For "special local concern" data requests, the state's authority to refuse registration is preserved. It need not act until after submission and review of the data. (Page 53, line 21.)

The applicable time limits for other application reviews are:

a. 120 days after receipt of the company's application and data if the pesticide is restricted, agricultural use, or contains a new active ingredient.

b. 60 days from receipt of the application only for all other pesticides.

8. Where a state requests data from a pesticide company to determine its hazards or efficacy, and the EPA vetoes the data request, the state cannot refuse to permit the sale and

use of the pesticide based on lack of the requested data.

(Page 54, lines 3-7.)

Analysis: This section would create an incongruous situation. Under Section 24(a)(1), a state could refuse to register a pesticide because it feared the potential to cause a particular disease, even though no test data had been submitted. However, if the state sought such data, and EPA vetoed, the state could no longer refuse to register that pesticide (at least based on that concern). Inquisitive states are thus penalized.

C. Conclusion.

Section 24 of the Act has worked well for many years. It should not be amended. It is particularly ironic that H.R. 5203 would saddle the federal EPA with new responsibility and seek to limit state authority at a time when EPA's budget is being severely cut, and power is supposed to be flowing from Washington to the states.



National Audubon Society

NATIONAL CAPITAL OFFICE
643 PENNSYLVANIA AVENUE, S.E., WASHINGTON, D.C. 20003 (202) 547-9009

Statement of Maureen Kuwano Hinkle, National Audubon Society Policy Analyst, before the House Committee on Agriculture, Subcommittee on Department Operations, Research, and Foreign Agriculture, on February 4, 1982, on H.R. 5203

The National Audubon Society opposes the major, proposed amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as set forth in H.R. 5203. The only meaningful change proposed by H.R. 5203 that would benefit the public is the private right of action under Sec. 16. The only other change necessary for these reauthorizing amendments, in our view, is a provision for extension of the Scientific Advisory Panel with staggered terms specified for Panel members.

Private right of action

Audubon is pleased to see the proposed amendment to Sec. 16 of FIFRA which provides for a private right of action, enabling citizens to bring suit for damages, attorneys fees and costs, and witness fees. (p. 46, lines 15-19)

Until the recent Supreme Court ruling (California v. Sierra Club, April 28, 1981) we assumed that private parties would have remedy for injury suffered by reason of a violation of FIFRA. Without a specific provision, however, the Supreme Court ruled that a private remedy is not implicit. Audubon therefore urges that this explicit provision be included in the Reauthorization of FIFRA.

Additional features of H.R. 5203 which Audubon supports

Sec. 3 would be amended by H.R. 5203 (p. 12, lines 8-19) to allow environmental groups to go directly to the Court of Appeals when the Administrator decided not to cancel a pesticide, but only after an "interim administrative review." Review by the Court of Appeals is desirable, but if EPA does not conduct an interim administrative review, private organizations do not have a viable alternative. H.R. 5203 does not give outside groups standing to sue, as we had argued for in earlier hearings.

H.R. 5203 also provides for reentry standards to protect farmworkers and those working or living in and around pesticide-treated areas. (p. 55, lines 8-19) Audubon supports this provision. Without provision for adequate resources to enforce the regulations and a priority deadline, however, standards and buffer zones are likely to be delayed indefinitely.

Section 3

The anti-competitive aspects of FIFRA as amended in 1972 is encouraged by the currently proposed Sec. 3 amendments (pp. 5-30). Throughout these hearings, members of this subcommittee expressed concern over the anti-competitive aspects of the amendments. The National Audubon Society shares this concern.

Earlier it seemed that the amendments proposed for Section 3 were arrived at unanimously by large and small companies. Since that time, it has come to our attention that not all of industry agrees that the compromise struck by this subcommittee is desirable. In addition, the Justice Department attorney

who litigated the Sec. 3 (c) (1) (D) and Sec. 10 cases, wrote a memorandum stating that the proposed amendments for these sections are unnecessary, anti-competitive and prohibitively complex. Should these objections not surface elsewhere at this hearing today, Audubon wishes to call them to your attention.

Chemical companies complain that they must undertake expensive reregistration requirements that should confer additional exclusive rights. For the entire duration of the 17-plus years of patent and exclusive use protection, the companies enjoyed profits often at minimum cost. The great majority of the important agricultural pesticides were patented between 1945 and 1965, many as a result of military research during World War II. Patents on many of the major pesticides have recently expired.^{Yet} despite the expiration of patent rights, the original registrant often continues to control the market. Enclosure A (letter from the president of the Drexel Chemical Company) details how several companies have continued to control the market after patent expiration.

In a memorandum, written shortly before H.R. 5203 was printed, a Justice Department attorney objected to any changes in the existing FIFRA Sections 3 and 10 as follows.

"I believe that the draft amendments to those sections are unnecessary and will result in needless complication of an already over-complicated regulatory system for registering pesticides which in turn will undoubtedly generate further litigation.

. . . The proposed expansion of Section 3(c) (1) (D) is wholly unwarranted. It will obviously greatly increase the anticompetitive effect of Section 3(c) (1) (D) and will impose greatly increased administrative burdens on EPA while at the same time making the pesticide registration process prohibitively complex for most applicants. Moreover, the purported need to promote research and development which serves as the justification for this provision is wholly illusory because, 'despite' the existence of the current, more limited version of Section 3(c) (1) (D), investment in pesticide research and development is booming. In any event, as in the case of Section 10, I believe it is inappropriate to change Section 3(c) (1) (D) and open it to a further round of challenges when the validity of the present section has been upheld by every court which has addressed the merits of challenges to it.

. . . In conclusion, I believe that the dramatic changes to Section 3(c) (1) (D), Section 3(c) (2) (B), and Section 10 contained in the draft House bill are unwarranted and unnecessary. Those amendments would not only geometrically increase the complexity of the pesticide regulatory process, but have a strong anticompetitive effect in the already highly-concentrated pesticide industry. More importantly, there is little economic justification for these amendments since the pesticide industry is currently expanding its already intensive research and development efforts notwithstanding the existence of the current law. Therefore, in my opinion, the current law should remain in effect and be allowed to operate as Congress intended." (emphasis supplied) */

USDA's Economics, Statistics and Cooperative Service published a report in September, 1980, that increasing research and development costs contributes to further industry concentration. Fewer companies account for a larger share of the pesticide market. Not only should this subcommittee be mindful of monopolistic aspects of FIFRA, other committees of the Congress should be made aware of the anti-competitive aspects of this legislation.

*/ Pesticide and Toxic Chemical News, Dec. 2, 1981, at 24.

Finally, commercial harm has been cited as a basis for change in Section 3(c)(1)(D). No change is necessary. Support for no change can be found in an opinion rendered by the EPA General Counsel on this issue dated March 5, 1976.

Nor is there a likelihood that disclosure of such test data will cause substantial harm to the data originator's competitive status because of use of the data by another firm in a pesticide registration proceeding in a foreign country. Much of the data, I am informed, would simply be inapplicable to registrations in other countries. Also, the registration requirements, if any, of other countries vary widely from FIFRA's requirements. I conclude that the possibility that a firm would suffer substantial harm in this respect is so conjectural and remote that it is not a factor which should be allowed to override the public policy expressed in S3(c)(2) favoring disclosure of test data to foster independent scrutiny of the decision to allow a pesticide to be used in this country. */

The disclosure provision, Section 3(c)(2), is taken up with Section 10, since it relates to trade secrets.

Section 10 (pp. 32-42 of H.R. 5203)

Changes proposed by H.R. 5203

H.R. 5203 provides for an elaborate mechanism to deny access to the public of health, safety and environmental information. Extraordinary penalties are imposed for release, acceptance or use of such studies. Incomprehensively, there are no disincentives for commercial espionage which was the

*/ Memorandum from Robert V. Zener to Edwin L. Johnson, dated March 5, 1976, re: Extent to which FIFRA Sec. 10(b) requires EPA to afford confidential treatment to test data.

original reason given for industry's request for a change in this section.

In 1978 trade secrets were defined as the formula, manufacturing processes, methods for testing, detecting or measuring inert ingredients in the formula, as well as production quantities. H.R. 5203 appears to give confidential status to studies submitted in support of a registration.

This section of the proposed amendments may be the most harmful to the public. All persons must apply for a library card to gain access to information submitted to EPA in support of pesticide registrations, which would be available only in EPA reading rooms. If granted access (there is no judicial appeal for denial), a person could borrow or remove studies, but could not disclose these, or make them available, to any other person. They also could not be used in judicial proceedings. The only usable information allowed are handwritten notes, and xeroxed tables and charts. These could be used for hearings, publications, medical treatment or evaluation of health effects. (page 40)

The penalty section imposes a fine of \$100,000 for each document or study accepted by a person with a library card. (p. 44, 1.8)

The same penalty of \$100,000 can be imposed on a person who intends to defraud or uses or reveals information on formulas of a compound.

A person who leaks information that is prohibited can also be fined \$100,000.

Audubon's position on disclosure of health, safety and environmental data

Audubon favors no change in the 1978 amendments. In our July 22, 1981, testimony, we suggested imposition of strong penalties for intentional commercial use of disclosed data. Intentional commercial use is obviously not a problem, and therefore no change needs to be made to Section 10.

Prior to 1972, the USDA's Pesticide Registration Division (PRD) refused to give outside scientists or other members of the public access to safety data on pesticides. Throughout the years after World War II when pesticide use was expanding, the scientific community was foreclosed from assessing the benefits and risks of pesticides because USDA regarded all data as "trade secrets." When challenged, USDA claimed safety data were intermingled with formulas and other confidential data and thus nothing could be released.

Inaccessibility to this information produced a great deal of public anxiety and suspicion of registration decisions. The Fountain Committee held extensive hearings, concluding

"The USDA Pesticides Regulations Division failed almost completely to carry out its responsibility to enforce provisions of (FIFRA) intended to protect the public from hazardous and ineffective pesticide products being marketed in violation of the Act."

The Congressional Government Accounting Office (GAO) also

conducted numerous investigations of pesticide decisions. The prestigious blue ribbon commission of the Secretary of Health, Education and Welfare (The Mark Commission) published in 1969 what has become known as the bible of pesticide information, "Pesticides and Their Relationship to Environmental Health."

As a result, authority over pesticides was taken away from USDA in 1970 and given to the newly created EPA. In addition, passage of a comprehensive package of amendments gave the new EPA greater regulatory authorities, together with deadlines, enforcement directives, and access to data submitted in support of registrations.

Section 3 of the 1972 Amendments requires the Administrator to make available to the public, within thirty days after registration, the data called for in the registration statement, except for trade secret data protected under Section 10(b).

The legislative intent underlying Section 3(c)(2) was "to promote independent scientific criticism and analysis of the data upon which an EPA action was based, and thereby to open to public review the exercise of this important administrative function." (Zener. memo at 5) The Senate Committee on Agriculture explicitly stated that it "provides adequate public surveillance of the Administrator's action" (S. Rep. 92-939, 92nd Cong., 2d Sess. (1972), Part 2, p. 36)

Even NACA testified in 1971 that "the data will be subject to appraisal by all interested parties as to its validity." (S. Rep. 92-939, 92nd Cong., 2d Sess. (1972), Part 2, p. 19)

Thus, the General Counsel in 1976 concluded that Section 3(c)(2) "deliberately provided a mechanism for promoting . . . scrutiny and criticism" of applicants' claims and EPA's registration decisions. Very explicitly, he said, "Accordingly, I conclude that Congress intended that all such data were to be disclosed under §3(c)(2), and that Congress thus did not intend such data to be protected by §10(b)." (Zener memo at 9) Disclosure, however, was not implemented since companies, notified of each request, routinely designated all information except labelling as "confidential."

In 1976 the Kennedy Committee on Administrative Practice investigated EPA and FDA approvals of compounds and found many to be falsified and misleading. After indictments of several laboratories, pressure mounted to amend FIFRA to provide for release of health, safety and environmental studies to the public. Though the disclosure amendments were agreed to by both Houses of Congress, chemical companies, in the hope of getting Section 10 ruled unconstitutional, added trade secret disclosure to ongoing data compensation litigation. These ten court suits effectively prohibited disclosure of information and implementation of Section 10 until resolution of the litigation. In June, 1981, three

courts rejected constitutional challenges to Section 10, and essentially told the chemical companies they should change the law if they didn't like Section 10.

The cost of implementing Sec. 10 of H.R. 5203 would be prohibitive.

Even while EPA has yet to separate out bona fide trade secrets from disclosable health and safety data, H.R. 5203 would set up reading rooms to make data available to the public. EPA's estimate for "scrubbing" the data is four - five years at a cost of \$5-10 million dollars. Manpower costs to the EPA would be 140 man-years, and to industry 50-100 man-years. The actual duplication on to microfiche would be about \$100,000 for ten sets. Thus, despite any amendments to Sec. 10 EPA would still be ^{or} a request-based system, precisely because of resources. (House hearings, Committee on Agriculture, 97th Cong., 1st Sess., June 16, 1981, July 16, 1981, July 22, 1981, Part 1, p. 601) The cost to EPA and to industry of a loss of public confidence in their decisions should also be factored into any change proposed for Sec. 10. Serious public anxiety and suspicion regarding federal registration decisions only hurts industry and the agency regulating it.

Benefits of disclosure under Sec. 10 of the 1978 Amendments

On the positive side, I wish to quote from a law review article written by a professor who testified on Sec. 10 at the July 16, 1981, hearings.

" . . . disclosure should improve agency effectiveness, permit better informed consumer choice, avoid wastefully duplicative testing, and promote scientific innovation.

1. Agency Effectiveness. - An agency faces a difficult task in predicting the likely social consequences of a product's use solely on the basis of experimental testing data submitted by the product's proponent. Data are often scientifically inconclusive, permitting reasonable scientists to arrive at different interpretations. Proper regulatory decisionmaking therefore requires the exercise of "scientific judgment." In addition, test sponsors, because of their financial interest in agency approval, often will design and report studies in the light most favorable to their products. After a product is approved, agencies rarely have the time and resources to reevaluate the original test data in light of changing scientific evaluational criteria. Thus, questionable industry interpretations can remain undetected for years.

. . .

Nondisclosure also may foster a pro-industry bias in agency decisionmaking. Where health and safety data are withheld from the public, industry representatives confront overworked agency personnel under conditions where there is no opportunity for independent observers to scrutinize the existing data and advocate their own inferences based upon their independent policy judgments. As a result, the agency is more likely to accommodate the objectives of its regulatees and perhaps expose the public to serious health risks.

In an open system, by comparison, the agency would not be deprived of the pluralism that is vital to the exercise of informed scientific judgment." */

*/ McGarity, T. O. and S. A. Shapiro, The trade secret status of health and safety testing information: reforming agency disclosure policies. Harvard Law Review, 93:5, March 1980, 837-888. from 840, 841, 843.

Thus, despite clear legislative intent and previous agency interpretations, it is disclosure of health and safety information to the public that has been sabotaged, not industry. Any change in Section 10 should only direct EPA to disclose health and safety information forthwith.

Section 24 - Authority of the states

In contrast to current policies giving states more authority over government functions, H.R. 5203 imposes complicated restrictions on how a state may regulate within its boundaries. National Audubon opposes these restrictions, and urges no change in Section 24(a).

The legislation as proposed by the 1971 Republican Administration explicitly honored states rights:

Nothing in this Act shall be construed as limiting the authority of a State or a political subdivision thereof to regulate the sale or use of a pesticide within its jurisdiction insofar as such regulation does not permit such sale or use as is prohibited under the authority of this Act. (Senate Subcommittee Hearings on S. 745, subcommittee on Agricultural Research and General Legislation of the Senate Committee on Agriculture and Forestry, 92nd Cong.)

From the start, Congress intended federal and state registration programs to coexist, with the federal registration requirements as the floor, not the ceiling for regulation. This explicit intent was articulated by the Republican Administrator in 1971 as follows:

I would like to emphasize that the States have played a major and continuing role in pesticides regulation. To date, 48 States have programs covering the registration or use of pesticides or both. We wish to encourage and not supplant these efforts. States are not precluded from imposing stricter standards or added requirements, but they may not permit any sale or use of a pesticide which is prohibited under the authority of this act. ((Senate Hearings on S. 745 at 29)

Specific preemption language was rejected by the House after floor debate. (117 Cong. Rec. 40044 (1971)) The present language of 24(a) was clearly intended to subject federally-registered pesticide products to state registration requirements.

It is precisely because several states have begun to realize that the Federal government has failed to regulate adequately that requirements have been imposed prior to state registration. Unfortunately, EPA registration is not a guarantee of safety, since studies required to make a relative safety determination for most pesticides have not been completed. If a state wishes to require health studies before exposing residents, it should be allowed to do so.

Section 25(d) - Scientific Advisory Panel

H.R. 5203 (pp. 54-55) merely extends the terms of members of the Scientific Advisory Panel. Representatives Fithian and Wampler were responsible for mandating the Scientific Advisory Panel in 1975 to provide advice to EPA on scientific and technical aspects of all regulatory pesticide decisions. For five years the original panel members served conscientiously, impartially, and knowledgeably. Termination of the Panel on September 30, 1981 was overlooked in these hearings. Yet the new Administrator of EPA dismissed all seven panel members, and appointed an entirely new slate.

Staggered terms is of course an obvious recommendation. In addition, this subcommittee should exercise more oversight of panel deliberations for the next two years. An entirely new panel will take that long to begin to understand how the very technical and complex process works on any given regulatory decision. The review and analysis intended by this subcommittee in establishing the Panel may take a while. In the meantime, many of the decisions EPA must make are very political: 2,4,5-T, ferriamicide, toxaphene, ethylene dibromide, and 1080. The Panel should not be allowed to be politicized.

Conclusion

Not since the 1971-72 hearings on FIFRA has this subcommittee heard from such a great variety of witnesses. We congratulate the subcommittee for encouraging and seeking such breadth and depth of input for these hearings. Despite this input and a great deal of work, we believe that H.R. 5203 would construct a most complex, confusing and unworkable scheme that would benefit noone. Therefore, except for Sec. 16 and 25(d), we urge a simple reauthorization of FIFRA.



Drexel Chemical Company

December 1, 1981

Senator Jesse Helms
4213 Dirksen Building
Washington, DC 20510

Dear Senator Helms,

For the past 6 to 8 years, almost all pesticide labeling in the U.S. has been virtually halted. This is due to numerous suits filed by both major domestic and international corporations against our United States government to block our U.S. Environmental Protection Agency from using data held in their files and authorizing pesticide labels for new producers and suppliers. This action allowed many major corporations to extend their 17 year patents, in many instances, by another 6 to 8 years. During this period, while the original patent holder continued to enjoy additional labeling based on data gathered at the beginning or during their 17 year patent, smaller corporations were blocked from entering markets normally available to them after the expiration of a U.S. patent.

Examples:

- I. Ciba-Geigy Corporation - "Atrazine, the major U.S. corn herbicide". This patent expired in 1976. Ciba-Geigy is still selling 70 to 80 percent of the U.S. market. This market has been controlled as follows:
 - A. Ciba-Geigy has sued the U.S. government to prevent the Environmental Protection Agency from issuing new atrazine labels.
 - B. We believe Ciba-Geigy has joined with Degussa Chemical Company to control, on a world wide basis, the sale and price of cyanuric chloride, the major intermediate utilized in production of atrazine.
 - C. Ciba-Geigy has threatened to sue smaller companies for data compensation if they should label atrazine and enter the U.S. market.
 - D. One U.S. company, Vertac Chemical Company, Vicksburg, Mississippi, was forced to close an atrazine manufacturing plant due to high cost of cyanuric chloride, supplied by Degussa Chemical Corp. Degussa Chemical Corp. chose Shell Chemical Company, another multi-national corporation, to enter the U.S. market to control the U.S. market between Shell Chemical Company and Ciba-Geigy Corporation on atrazine.

Ciba-Geigy's total atrazine profits and profit margins are now, we believe, similar to the profits they enjoyed 6 years ago, when they held a U.S. patent. Net result, Ciba-Geigy has enjoyed a 6 year patent extension.

"Diazinon", another Ciba-Geigy pesticide, where the patent has expired, and the situation is similar to atrazine only this product is much smaller in dollar volume.

- II. Union Carbide Corporation. This large U.S. corporation held a patent on the pesticide trademarked "Sevin". The U.S. patent expired several years ago and today Union Carbide still enjoys 100% of the U.S. market. This market is reportedly approximately 25 million pounds or approximately 56 million dollars in sales. Union Carbide can well afford to spend a few hundred thousand dollars a year in law suits to protect a 25 million dollar gross profit market. Union Carbide, like Ciba-Geigy, has sued our federal government to prevent the use of any Union Carbide data in approving competitive labels. Union Carbide has also been very active and successful in preventing the importation of "technical" Sevin into the U.S. We have been informed that Union Carbide has not really spent any money on data since 1970. Net result, Union Carbide has enjoyed another 6 or so years on top of their 17 year patent with no competition or another way to state it might be, they have received an additional 72 million dollars in profit.

- III. Mobay Chemical Company, Stauffer Chemical Company, Du Pont Chemical Company, Dow Chemical Company, Rohm and Haas Chemical Company, FMC Corporation and many others have all brought suit against our federal government under the guise of protecting trade secrets and proprietary data, when the real goal was to protect large profitable pesticide markets that were already or just coming off patent.

Senator, these large multi-national corporations have for the past 6 to 8 years been well rewarded for the unethical tactics and questionable legal maneuvers. In many instances it has been rumored the basic producers have been indirectly responsible in creating public concern causing the U.S. government to ask for data only the original patent holder would be able to afford to supply. The cost of supplying additional data is peanuts to these large multi-national corporations as it represents only a small percent of their annual profits on the specific pesticide involved.

Historically, the major corporations relied on new, patented products to replace the older ones coming off patent. Now they would have you believe the expense of developing and labeling new products is becoming prohibitive. We agree the development cost is up but the large corporations relative position has greatly improved due to the large potential U.S. markets. Ciba-Geigy's "atrazine" has sales in the U.S. of approximately 200 million dollars. Elanco's "Treflan" and Monsanto's "Lasso" are vast markets of similar dollar value.

A partial effect of these restrictive regulations and lawsuits in the area of pesticide registrations is already apparent of several products where U.S. formulators and consequently farmers, are paying substantially above world-market prices for commodity pesticides. Specific examples of pricing at the distributor level include Methyl Parathion at \$1.35 per pound in the U.S. versus \$0.88 to \$0.90 per pound on the world market, Maneb at \$1.40 per pound versus about \$1.00 per pound, Sevin at \$2.12 per pound versus \$1.75 per pound and Toxaphene at \$0.635 per pound versus \$0.48 per pound. Without the ability for smaller companies to obtain necessary labels on world quality materials, there is no reason for the major corporations to price their commodity products at competitive levels in the U.S. They will, however, price their products competitively in overseas markets where they face the direct competition from other suppliers. The negative effect of these actions on our agricultural and over-all economy are apparent.

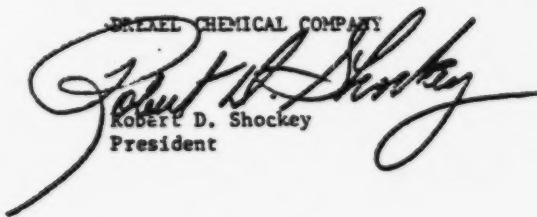
The most damaging thing that can happen to our free enterprise system would be to allow these great corporations to continue to monopolize these old commodity markets by having our U.S. government allow the exclusive use of data that was mostly gathered under the protection of U.S. patents over a 17 year period.

We believe efforts underway to modify current patent laws to extend the patent life is unwise. Our current 17 year patent laws are very adequate to give any U.S. corporation the incentive to develop new potential products. To enact legislation allowing these large companies, the right to continue a monopoly will not be an incentive but rather a deterrent as they will not develop new products as long as they are allowed to continue the old monopolies.

We are most anxious to learn why you support these giant corporations at the expense of smaller corporations like ourselves.

Sincerely,

DREXEL CHEMICAL COMPANY


Robert D. Shockey
President

RDS:eb

A boost for the Alaska natural gas pipeline

Prospects are brightening for Congressional acceptance of White House proposals that could promote the private financing of the \$40-billion, 7,800-mi Alaska natural gas pipeline. Less than a month after the Reagan Administration asked Congress to consider the package, the Senate Energy Committee approved it by a 15-1 margin. It now goes to the full Senate for a vote that is expected to be equally favorable. In the House, where the package is more controversial, opposition has been softening despite continued pressure from consumer-minded legislators. The main sticking point is whether to waive conditions set in 1977, when President Carter allowed the project to go forward. That would permit the natural gas companies sponsoring the project to charge their customers added rates to pay off debts if the project is delayed or canceled. Outweighing that consideration, at least so far, has been a groundswell of support for the project for reasons of national security. Reserves of Alaskan gas amount to more than 26 trillion cu ft, and this is being held up as an important enough supply of fuel to warrant higher costs. A House vote is expected soon.

Auto makers may collaborate on pollution control

The Justice Dept. has decided that U.S. auto makers should be permitted to collaborate in developing pollution-control devices. Such cooperation was banned by a 1969 consent settlement of a government antitrust case charging that General Motors, Ford, Chrysler, American Motors and the predecessor of the Motor Vehicle Manufacturers Assn. conspired to curb competition in emission controls. But Justice now agrees with the companies that the prohibitions may actually hurt car buyers by inhibiting adoption of new clean-air techniques. The department and the companies are asking the U.S. District Court in Los Angeles to drop the ban on cross-licensing agreements among the companies, on joint arrangements to assess the value of patents held by others, and on agreements to limit publicity about pollution-control research. For the next five years, the companies would have to report details of any such agreements to Justice, and, the antitrusters emphasized, the Sherman Act provisions against a conspiracy to keep any particular device off the market will still operate.

The decline in natural gas reserves is halted

After years of declining oil and natural-gas reserves, the U.S. position remained virtually unchanged in 1980, according to a recent Energy Dept. report. Increased drilling activity prompted by crude decontrol and higher gas prices offset consumption. The

report, issued by DOE's Energy Information Administration after a lengthy delay, found proved reserves—those that can be economically recovered—for oil as of Dec. 31, 1980 to be 29.8 billion bbl, the same as they had been in 1979, EIA said. Natural gas reserves were down by just under 1%, at 199 trillion cu ft as of the end of 1980. That compares with an annual decline of nearly 5% from 1976 to 1979. Reserves of natural gas liquids declined by about 2%, to 6.7 billion bbl. The reserve data, taken from a sample of more than 17,000 oil and gas wells active in 1980, were called "very significant" by EIA Administrator J. Erich Evered, who said they show "that rapid depletion of our proved reserves can be avoided" through higher levels of exploratory drilling.

Helms backs protection of pesticide data

Advocates of increasing data protection from 10 years to 15 years in pesticide registrations have picked up key support from the chairman of the Senate Agriculture Committee. Jesse Helms (R., N.C.) told the Chemical Manufacturers Assn last week, "You and others are justifiably concerned about the exclusive use of data under the Federal Insecticide, Fungicide and Rodenticide Act. The present right of a manufacturer to the exclusive use of any developmental data for 10 years is demonstrably not long enough to encourage the investment of necessary capital for research, development and registration of new agricultural chemicals," Helms said. "When this question comes before the Senate Agriculture Committee, I will give priority to working something out to give our agricultural industry the protection and incentive it needs," he added. Hearings will be scheduled soon.

Shipments of high-level nuclear wastes are rising

Increasing volumes of high-level radioactive-waste shipments will begin moving along U.S. highways in 1986, according to a draft study by the National Academy of Sciences. Copies of the study, released by the Environmental Policy Institute, show that more than 100,000 spent-nuclear-fuel assemblies will need to be shipped by the year 2004, as current storage space at power plants runs out and new disposal facilities are built. NAS noted that centralized storage sites will mean shipments of spent fuel through regions with no nuclear power plants of their own, requiring state and local governments to establish their own regulations. More than 211 cities, counties and states already have passed laws for the routes to be used for transporting nuclear materials. But the Reagan Administration is considering a federal preemption that would wipe out those laws.



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SUMMARY OF FIFRA HEARINGS, FEBRUARY 4, 1982

John E. Blodgett
Specialist

Environment and Natural Resources Policy Division

March 18, 1982

Ever since the Federal Insecticide, Fungicide, and Rodenticide Act was rewritten in 1972, Congress has been importuned for adjustments in the statute. The last substantial amendments were enacted in 1978, and authorizations were extended through FY1981 in 1980. A simple reauthorizing bill for FY1982 has been reported in both the House (H.R. 3271) and the Senate (S. 1036). No final action has occurred, however, and various additional amendments to FIFRA are being considered.

These amendments reflect the concerns of numerous groups affected by FIFRA, as brought out in a series of five hearings by the House Subcommittee on Department Operations, Research and Foreign Agriculture during the summer of 1981. ^{*}/ Draft amendments were discussed at four Subcommittee markup sessions during the autumn of 1981, and a "clean bill" (H.R. 5203) was introduced in December 1981. On February 4, 1982 a hearing was held to solicit the views of the various concerned interests on the amendments as incorporated in that bill.

This paper summarizes the witnesses' views on H.R. 5203. Most of the witnesses had testified at one or more of the earlier hearings, where their basic positions on the issues were recorded. The import of the February 4 hearing therefore lies in the position the witnesses took with respect to the specific language of the amendments as contained in H.R. 5203.

The issues covered by H.R. 5203 fall into two groups: a group of

^{*}/ The issues are explained in more detail in "Summary of Hearings on the Federal Insecticide, Fungicide, and Rodenticide Act—1981" prepared by CRS (September 21, 1981).

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three substantial amendments--concerning data for registration, access of the public to health and safety data, and State authority to require data for State registrations--and a group of miscellaneous amendments that, while important, have generally not been at the center of debate. Only the first group is reviewed here.

SUMMARY

The three major proposed amendments originated from industry complaints, and each was spearheaded by one of the pesticide manufacturing associations--section 3 registration changes by the Pesticide Producers Association, section 10 protection of registration data by the National Agriculture Chemicals Association, and section 24(a) State registration provisions by the Chemical Specialties Manufacturers Association.

George Miller, Pesticide Producers Association, seemed to feel that the H.R. 5203 amendments to section 3 were, with a few qualifications, acceptable--and essential:

We do know that our membership needs the changes in section 3, as does the rest of the industry. We would like to see as complete a bill as possible be reported out of the subcommittee; however, we request the subcommittee give serious consideration to passing section 3 no matter what else may happen to the rest of the bill. [p. 122]

Jack Early, National Agriculture Chemicals Association, testified that the H.R. 5203 amendments to section 10 have been compromised and rewritten until they are no longer satisfactory; he suggested that a new effort at resolution is needed:

... we started out with the reading room, and we stayed in the negotiation process for many, many months. We have compromised issues all down the line and we have seen our positions gradually

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cut away, cut away, cut away. Somewhere in late November and December I got the strong feeling I was no longer compromising but I was capitulating to a position that no longer satisfied my members' interest out there. We have moved too far over, and that was when we raised the question, "Are we going to be better off with H.R. 5203 ... than what's in the existing statute?" Obviously neither one of them are acceptable.... I'd like to ... give the regulating agency which has to deal with this under the new Administration a chance to look ... and see if they can't ... come back with some magic solution.... [pp. 109-110]

Ralph Engel, Chemical Specialties Manufacturing Association, felt that the H.R. 5203 amendment to section 24(a) was acceptable and essential: asked "if there were no change at all provided [in section 24(a)] and simply a reauthorization of the Act as it exists now, what would be the posture of the industry ...?" Engel replied:

We would be opposed to it because we feel that we have indeed in good faith compromised our position to the point where it is fair and equitable to all, including the States and the industry and the government. We would definitely be opposed to that position. [p. 53]

Representatives of farmworker and chemical unions; of health, environmental and other public interest groups; and of States opposed the section 10 and section 24(a) amendments of H.R. 5203. Most of these witnesses did not address the major section 3 amendments. These witnesses did support several miscellaneous amendments, the most important including provisions to give greater public access to regulatory decisionmaking and a proposal to add a private right to sue. Maureen Hinkle, National Audubon Society, concluded:

I regret that despite this input and a great deal of work on everyone's part that H.R. 5203 is too complex and confusing and unworkable.

So, therefore, except for sections 16(e) [concerning private right to sue] and 25(d) [concerning the Science Advisory Panel] we urge a simple reauthorization of FIFRA. [p. 224]

The Environmental Protection Agency, represented by John Todhunter, concluded: "... our experience thus far has not revealed any compelling

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reasons for changing the law at this time." [p. 125] However, because of the expiration of authorizations and of the authority for the Science Advisory Panel, he said: "I would respectfully urge the subcommittee ... to obtain enactment of the already reported bill [H.R. 3271] regardless of the action the committee takes on H.R. 5203." [p. 133] Finally, Todhunter observed:

One of the problems the Agency has had over time with the administration of FIFRA is that just when the Agency thinks it knows what it is doing, the law is changed again. This law has been amended and amended.

Our basic concern is that we are not sure until we have clearly identified a better way to do something that we should go in and change the law.

Certainly ... [once] this Administration has had a chance to implement and make ... administrative fixes ... we will know better whether we need to fine tune it legislatively. [pp. 158-159]

THREE MAJOR FIFRA ISSUES

1. Data for Registration. Three problems in FIFRA's section 3 concerning registration are addressed in the amendments: (1) extending to 15 years the period during which a firm has "exclusive use" of registration data and phasing out "compensation" for data use by others; (2) providing that a firm need not "cite all" the data of another firm when registering a pesticide partly on the basis of that firm's data; and (3) establishing procedures for allocating among firms the costs of preparing "defensive data" for existing registrations. Generally, these issues have been seen as internal industry problems regarding entry into the industry, competition, etc.

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George Miller, Pesticide Producers Association, strongly supported the section 3 amendments, with only minor qualifications (e.g., questioning the need for an 18-month phase-in period). Jack Early, National Agricultural Chemicals Association, concurred. Theodore Reuter, Reuter Laboratories, described how the "cite all" provision as implemented by EPA was adversely affecting his firm and urged enactment of an amendment.

Maureen Hinkle, National Audubon Society, said "we oppose section 3 changes as embodied in H.R. 5203" primarily because of "concern over the anti-competitive aspects of these amendments." She noted that the section 3 amendments were not a unanimous compromise, and she referenced a letter from a chemical company objecting to any changes in section 3. Also, she cited a Justice Department attorney who had litigated some section 3 cases and who had written "that the proposed amendments ... are unnecessary, anti-competitive, and prohibitively complex." [p. 220]

John Todhunter, Environmental Protection Agency, noted several difficulties with the section 3 amendments. Basically, he stressed that "additional complications to section 3 will work against our efforts to speed up registration actions and reduce backlogs and paperwork." He noted that the extension of "exclusive use" to new uses would add the most complexity. He said the "provision raises anti-competitive concerns." In summary, he said, "In FIFRA terms, it seems to me that the benefits of such a system to industry incentive may be outweighed by the administrative complexity and burdens that the system will impose." [pp. 127-128] Asked whether the "cite all" problem could be resolved administratively, Ed Gray of EPA said, "there are some legal risks in setting up a new system which is rather different from the present system without first being told by Congress that we should change the system." [p. 162]

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2. Public Access to Data. One of the provisions of the 1978 amendments to FIFRA was a system for making available to the public the health and safety data used in registration. Industry filed suits challenging the provision, but in cases so far decided it has been upheld. Industry therefore proposed changes, saying that access to the data was "anti-innovative" and needed to be circumscribed. A "reading room" where the data could be viewed was proposed, and H.R. 5203 would amend section 10 of FIFRA to set up regional reading rooms where the public could get limited access to health and safety data. The provision proved highly controversial.

Stephanie Bower, United Farmworkers of America; Richard Lewis, International Chemical Workers Union; Kirk Johnson, Center for Science in the Public Interest; Stephen Brobeck, Consumer Federation of America; Clyde Shorey, March of Dimes Birth Defects Foundation; Jacqueline Warren, Natural Resources Defense Council; Thomas McGarity, University of Texas School of Law; Tom Hecht, National Coalition against the Misuse of Pesticides; and Maureen Hinkle, National Audubon Society, all opposed the section 10 amendments as an unreasonable abridgement of public access to health and safety data.

Brobeck asserted "it is a fundamental right in a free enterprise system that consumers be informed. Congress should not impede public access to this important information. The current amendments in H.R. 5203 to section 10 do impede public access." [p. 78] He then summarized procedural problems, and concluded that they "would deny meaningful access to health and safety data. They would also deny a meaningful review of the data and subject the new section 10 provisions to endless litigation, essentially removing the provision from the statute." [p. 80] He also contested the

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industry view that disclosure of the data would cause significant losses.

Shorey said, "these amendments seriously undermine the scientific review of the effects of pesticides which could cause birth defects and other reproductive health problems." [p. 86]

Hecht stressed the procedural difficulties that the section 10 amendments would entail, including additional burdens on EPA, a lack of clarity in how one applies for information, uncertainties in screening who would use the rooms and under what conditions, and problems in controlling disclosure of data. [pp. 209-210]

Brobeck and McGarity both contended that the 1978 amendments established a proper balance between the interests for making public and for holding confidential pesticides registration data. McGarity said:

Dr. Todhunter testified that a legislative solution ... was probably necessary....

That legislative solution has been enacted in the FIFRA amendments of 1978. There the contending forces that are at play here were at play in 1978 and the resolution of that was that health and safety data with three well-defined exceptions ... were to be made public.

That is what Congress decided in 1978. Numerous pesticide companies have decided to appeal this decision ... [to] the courts, their contention being that section 10 of FIFRA, as amended, is unconstitutional.

The courts have not surprisingly rejected that notion....

This is precisely the wrong time to amend the statute. A good deal of that litigation is now coming to rest....

What we need to do now, I think, is simply get down to the business of administratively implementing a statute and allowing some of these health and safety studies to be examined by public interest groups and scientists and representatives of farm workers and so on....

That I would have thought was the bargain struck in 1978 and a heavy penalty was there for aiding in the obtaining of this data to be used overseas.... let us see if all this competitive harm that we have been told about will occur." [pp. 199-201]

Jack Early, National Agriculture Chemicals Association, argued that as now written section 10 of FIFRA would do serious harm to the domestic pesticide industry. He described how the "reading room" idea was presented

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as a "workable balance," but indicated he now felt that the procedures, as spelled out in H.R. 5203, had become unsatisfactory--no longer a compromise, but a capitulation. Early therefore recommended--

that the problem of data protection and public access be remanded to EPA for study and evaluation. We ask that this subcommittee give a mandate to EPA to find a reasonable administrative solution or recommend a legislative one--a solution that will accommodate both the need to protect the confidentiality of industry data from competitors and the public's interest in being informed as to risks and benefits of registered products. [p. 98]

He further suggested that while EPA was investigating alternatives, concerns about data raised by interest groups be investigated by the Scientific Advisory Panel of EPA.

Asked if he were "saying that you prefer to exist in the present chaos as opposed to moving this particular solution at this time?"

Early said:

Yes, we do but with a proviso. Before EPA or this Committee or the Congress arbitrarily releases our information, we are urging ... at least one more party who is going to administer the law to have a look at it and make recommendations. There are a lot of down sides for us asking for no change in section 10. It was a deliberately thought out decision. [pp. 114-115]

EPA's Todhunter said that the section 10 amendments could be implemented, but would impose costs and paperwork. He said EPA "would run the system on a request basis, and data would not be released more quickly than it is under the present procedures." He said, "Whether this system actually provides more protection for industry data than is currently available is questionable." [p. 128] He noted that Freedom of Information requests had been received and were being processed, with the Agency's general counsel assessing legal requirements. EPA's Gray said a memo had been prepared. Gray noted that regulations implementing the changes made by the 1978 amendments had not been prepared. He said:

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We have delayed formally changing the regulations because of the litigation that we have been involved in over the constitutionality of section 10.

Now that most of the courts seem to be saying that it is indeed constitutional, we think it is ripe to change the regulations.

However, we realize that we will not do it until it is more clear what will happen here in the Congress. [p. 170]

Todhunter concluded that "It is generally our belief that there probably is not an administrative solution to this dilemma. It probably requires some legislative solution." [p. 146]

3. State Requirements for Pesticides Registration Data. The third major issue addressed by H.R. 5203 concerns whether a State, in registering a pesticide, can request data beyond that used by EPA in registering it, and if so, whether the State should have to justify its request in some way. At present, as provided in FIFRA's section 24, a State can request additional information, and California has in place a registration program that has been upheld by the courts. Segments of the pesticide manufacturing industry have sought constraints on this power, saying that California's requirements have been excessive and unreasonable. Also, industry representatives say that it could someday face 50 State EPA's each requiring data according to its own specifications.

Leading the support for the H.R. 5203 amendment to section 24(a) was Ralph Engel, Chemical Specialties Manufacturers Association. He submitted that California had imposed unreasonable burdens on the industry in its requirements and he said other States appeared to be establishing new requirements. He stressed that the amendment was a compromise that left the present section 24(a) provisions intact, but provided that EPA could review State requests for additional data concerning nonagricultural pesticides. He said opponents to the H.R. 5203

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amendment to section 24(a) "were left with no more than a specious States' rights philosophical argument." [p. 46] Engel said that if H.R. 5203 were enacted without the section 24(a) amendment, he believed "it would trigger ... other States to move quickly into the arena ... and disrupt totally the national marketing efforts of many companies." [p. 53] Supporting Engel's position were Jack Early, National Agriculture Chemicals Association, and George Miller, Pesticide Producers Association.

Apparently there had been real problems with the California requirements, for Walter McGuire, California State Office, described changes in the California pesticides registration requirements designed to "address and take care of, to a large extent, the problems that have faced the manufacturers and the people who use pesticides in the State of California." [pp. 229-230] McGuire, along with James Grant, National Association of State Departments of Agriculture; Stephanie Bower, United Farmworkers of America; Stephen Brobeck, Consumer Federation of America; Clyde Shorey, March of Dimes Birth Defects Foundation; Jacqueline Warren, Natural Resources Defense Council; Tom Hecht, National Coalition against the Misuse of Pesticides; and Maureen Hinkle, National Audubon Society all opposed amending section 24(a). Grant said, "We do not believe that the current problem in one State should be solved by legislation that disrupts registration programs in the other 49 States." [p. 8] In response to a question asking whether other States were likely to begin extensive registration programs if section 24(a) were not amended, Grant replied:

... insofar as we have been able to determine ... there is no sort of movement under way and very frankly I doubt that there are many States that are geared up to have the technical set-up

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within their organization to get into that in-depth type of program, except California.

I personally do not feel that there is any kind of movement underway. Certainly the 50 State Departments of Agriculture are not interesting in creating 50 little EPA's out there, as has been said. [pp. 12-13]

EPA's Todhunter opposed the H.R. 5203 amendment to section 24(a).

He said the agency was "sympathetic" but "troubled by the proposed amendment as it bears on the prerogatives of the States. Further, we oppose the role of arbitrator between industry and the States thrust on the Agency by the bill, and this leads us to oppose the section 24(a) amendment."

[p. 130] In answer to a question, Todhunter said the California situation may not be a good model for the problem, "so, I am not sure, and the agency is not sure, that to propose a specific legislative amendment to correct a problem which exists in a limited fashion is worth the statement that the States must now report to us and allow us to tell them whether or not the request is reasonable." [pp. 159-160]

STATEMENT OF THE AFL-CIO ON AMENDMENTS TO THE
FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT
SUBMITTED TO THE SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH, AND
FOREIGN AGRICULTURE OF THE HOUSE AGRICULTURE COMMITTEE

February 4, 1982

The American Federation of Labor and Congress of Industrial Organizations has a direct and immediate interest in the reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act. Members of our affiliated unions face serious risk of disease, injury and death from the use, application and manufacture of pesticides. For farmworkers and pesticide applicators FIFRA provides the primary occupational health protection, though that protection is far from adequate. For these individuals and all workers exposed to pesticides, FIFRA provides the major if not sole avenue for gaining access to basic health and safety data on pesticide toxicities. It is this second area of protection -- access to information -- that will be the focus of these comments.

Information on the identities and potential risks of workplace chemicals is a primary concern of the AFL-CIO and its affiliated organizations. Members of AFL-CIO unions are routinely exposed to chemical substances on the job with little or no information about the effects of exposure. These workplace exposures have been and continue to be responsible for hundreds of thousands of cases of disease and death among exposed workers. Pesticide workers, unfortunately are no exception. In addition to routine poisoning of farmworkers, grain millers and longshore workers from pesticide application, scores of workers exposed unknowingly to pesticides in the manufacturing sector have suffered injury and harm. The

1973 and 1977 poisonings of chemical workers from exposure to kepone and DBCP are but two examples of the serious health hazards posed by pesticide exposure in manufacturing facilities.

For the past ten years the AFL-CIO has sought to gain "right-to-know" protections under applicable federal, state and local statutes. Chemical identification and some limited hazard information is required by 23 individual OSHA health standards through a system of labels and warning signs. Among these substances 2 pesticide ingredients, DBCP and inorganic arsenic, are included. A more comprehensive regulation providing toxic substance information -- the OSHA Access to Employee Exposure and Medical Records Standard -- was promulgated in 1980. This regulation does not require the generation of any hazard information, test data, or medical exams, but does impose a requirement that employers make available to employees and their representatives, upon request, copies of medical records and exposure records that are maintained. Industrial hygiene data and some epidemiologic studies are covered by the "Access" standard, but animal toxicity studies are outside the scope of this regulation. Workers in the manufacturing and construction industries are covered by the standard, but no protections are provided to agriculture workers.

A federal regulation to require the identification of chemical substances and their hazards by chemical manufacturers has been under development by OSHA for over seven years. However, the type of regulation under consideration and related state and local statutes on chemical hazards identification, do not require that any toxicity testing be conducted or that copies of health and safety studies be provided.

The Toxic Substances Control Act does theoretically require that toxicity testing be conducted for all new chemicals (other than chemicals

solely for use as pesticides), and that health and safety data submitted to EPA be made available for public disclosure. However, experience with TSCA to date shows that for over half the new chemical notifications, no toxicity data has been submitted.

These numerous statutes and regulations outlined above, have provided increased access to a variety of health and safety data over the past five years. However, Section 10 of FIFRA still provides the major if not sole vehicle for access to basic health and safety data on the effects of pesticides.

FIFRA serves as a major component of the federal/state right-to-know package. Therefore, proposals to restrict the right of access to health and safety data under FIFRA raise serious concerns not only for access to pesticide information, but the potential impact of such restrictions on other statutes. The TSCA statute and OSHA regulations are founded on the premise that the public health benefits associated with the disclosure of health and safety data outweigh confidentiality considerations of such disclosure. Any legislative changes in FIFRA that restrict access to pesticide information are certain to initiate attempts by the chemical industry to seek parallel restrictions on access to health and safety data under the TSCA Act, OSHA Act and related statutes.

The AFL-CIO recognizes that this subcommittee has made a good faith effort to address the stated, if undocumented problems of the pesticide producers regarding health and safety data disclosure while maintaining the public right of access to pesticide information. However, the provisions of H. R. 5203 which substitute the FOIA access procedures with a system of library cards, reading rooms and restrictions on information use do severely

impede meaningful access to health and safety data on pesticides.

The proposed system is highly bureaucratic and cumbersome. Borrowing privileges for most individuals are subject to industry review and EPA approval with no right of judicial review in the event that an application is denied. For approved users, copies may be made of charts, tables and graphs, but summaries and abstracts are excluded. Comprehensive notes may be made of reviewed studies and used for subsequent purposes, but the making of a hard copy is prohibited. Time frames established under these provisions indicate that requested data is unlikely to be obtained in less than a three to six month time period. For most unions seeking data for emergencies or other immediate health problems, such time frames make even the proposed data access meaningless.

The AFL-CIO believes that the current provisions of Section 10 of 1978 FIFRA Act provide a balanced workable approach for access to health and safety data, if administered properly by EPA. In our opinion, maintenance of the current Section 10 language would better serve the interests of workers and the public than substitution of restrictive provisions. Recognizing that the subcommittee may decide to proceed with some version of the concept embodied in the Section 10 amendments in H.R. 5203, we have, however, drafted changes to the proposed language which attempts to initiate some of the major problems posed by those amendments. (See attachment I.)

Though maintenance of the integrity of Section 10 and its data access provisions is the primary concern of the AFL-CIO, other amendments under consideration are also important. Section 24 amendments limiting the

ability of states to collect pesticide information and to take necessary regulatory action are ill-advised, particularly during this time of federal program cutbacks and return to the states philosophy. The AFL-CIO has generally favored the federalization of health and safety programs. However, where states do have authority and responsibility, federal statutes and regulations should not restrict states in their efforts to protect their citizens.

Unlike most other federal environmental statutes, the current FIFRA legislation contains no provisions to protect employees who exercise their rights under the Act from discrimination or retaliation. H.R. 5203 does provide some language prohibiting such discrimination, but no procedures are set forth to assure redress in the event discrimination does occur. The AFL-CIO has reviewed the Clean Water Act, the Clear Air Act, the Resource Conservation and Recovery Act and the Toxic Substance Control Act, all of which contain parallel language prohibiting discrimination and setting forth procedures for the handling of such claims. Of these four statutes, the RCR Act provides the simplest language on employee protection, and we recommend that the same language be adopted if there is any amendment to the 1978 FIFRA Act. (See attachment II.) Such language would be easily implemented, relying upon existing procedures and mechanisms established for these other statutes, and would only extend to pesticide workers the protection other workers are guaranteed under every other health and safety and environmental statute.

The AFL-CIO appreciates the opportunity to submit its views on the reauthorization of FIFRA. We are fully aware of the difficulties and conflicts posed by this legislation, but have every confidence that this subcommittee will take no final action that will compromise the health and safety of American workers or the public.

Attachment I

AFL-CIO
Proposal For
Section 10
January 26, 1981

1 preparing the final analysis of such impacts, the Ad-
2 ministrator shall fully consider all comments on the
3 proposal, including those provided by the Secretary.”

4 PROTECTION OF TRADE SECRETS AND OTHER
5 INFORMATION

6 SEC. 5. Section 10 of the Federal Insecticide, Fungi-
7 cide, and Rodenticide Act is amended by—

8 (1) amending subsection (a) to read as follows:

9 “(a) IN GENERAL.—In submitting data required by this
10 Act, the data submitter must clearly mark portions thereof
11 which in the opinion of the data submitter are trade secrets
12 or commercial or financial information, explain why each
13 marked portion is not required to be disclosed under subsec-
14 tion (d)(1) of this section, and submit such marked materials
15 separately from the other material required under this Act.”;

SECTIONS DELETED

Language of existing statutes stands

SECTIONS DELETED

Language of existing statutes stands

4 (2) redesignating subsections (d)(2) and (d)(3) as
5 subsections (d)(3) and (d)(4), respectively;

6 (3) adding a new subsection (d)(2) to read as fol-
7 lows:

8 “(d)(2) The Administrator shall make information that
9 may be disclosed under subsection (d)(1) of this section avail-
10 able through Environmental Protection Agency reading
11 rooms to be located at Environmental Protection Agency na-
12 tional headquarters and each of its regional offices. Such in-
13 formation shall be transmitted by the Administrator to the
14 regional offices as requested. All copies of data disclosable or
15 available in or from an Environmental Protection Agency
16 reading room shall remain under the control of the United
17 States Government.

18 “(A) Except for employees or agents of any
19 person engaged in, or which intends to engage in, the
20 production or registration of pesticides, or any other
21 person which intends to deliver data in violation of this
22 section to any employee or agent of any person en-
23 gaged in the production or registration of pesticides, all
24 members of the public, including employees of the
25 United States and agencies of State governments, shall

1 be permitted access to the reading rooms established
 2 pursuant to this section: *Provided*, That employees, or
 3 their agents, having jurisdiction over pesticide matters
 4 in any agency of the United States or a State govern-
 5 ment shall have access to the reading room even
 6 though the agency may be a pesticide registrant or
 7 producer: *And provided further*, That designated repre-
 8 sentatives of groups of employees, and individual em-
 9 ployees, of pesticide producers, who seek access to in-
 10 formation available for disclosure in connection with
 11 providing advice on the health effects of the pesticide
 12 or its ingredients to the employees or who seek access
 13 to information available for disclosure to
 exercise rights under this Act or other federal
 and state laws, shall be permitted access to the
 reading room.

14 "(B) Any person described in subparagraph (A)
 15 who wishes to make use of the reading room for any
 16 purpose shall—

17 "(i) state in writing the name, address, and
 18 occupation of that person and any other person
 19 which the person is representing, and a descrip-
 20 tion of the information, if any, which the person
 21 seeks to remove or copy;

22 "(ii) sign a statement that such person does
 23 not seek access to information for the purpose of
 24 informing any person engaged in the production
 25 or registration of pesticides of the contents of such

1 information and will not knowingly and willfully
2 cause such information to
3 be disclosed to any such person or its agents or
4 employees, except for information which may be
5 copied under subparagraph (C) of this paragraph,
6 and except to the extent such disclosure is made
7 in compliance with paragraph (G) of this subsection; and

8 "(iii) comply with rules and procedures established by the Administrator consistent with the
9 provisions of this section.

10
11 "(C) Subject to the requirements of subparagraphs
12 (B), (D), (E), and (F) of this paragraph, any person
13 having access to a reading room may—

14 "(i) take notes on any information available
15 for disclosure in the reading room;

16 "(ii) obtain on request from the Environmental Protection Agency at the reading room a copy
17 of complete studies and any charts, graphs, tables containing statistical data, summaries, or abstracts that may be contained in any study available for disclosure in the reading room;

21 "(iii) remove any notes and copies of the
22 foregoing charts, graphs, tables, summaries, or abstracts, from the reading room and retain
23 such material without returning it to the
24 reading room; and

2 room any other documents containing information
3 available for disclosure under this section.

"(D) United States nonprofit organizations, agencies of State governments, United States colleges and universities, United States medical practitioners and health and safety professionals, including those designated by groups of employees or individual employees of a pesticide producer as described in paragraph (A) of this subsection, and farm workers or their designated representatives, may remove any information available for disclosure from the reading room, including complete studies, after complying with the requirements of paragraph (B).

"(E) Any other individual or or-
15 ganization not otherwise restricted from access to a
16 reading room, may apply to the Administrator for per-
17 mission to borrow and remove any information availa-
18 ble in a reading room, including complete studies. The
19 Administrator shall grant such permission within not
20 more than 30 days after the application is received
21 unless the Administrator has determined that the
22 person should be denied permission pursuant to the
23 protections afforded data in subparagraph (G) of this
paragraph. If the Administrator has
reason to believe that release of the
requested information may result in an
illegal use of such information, as defined
by this Act, the Administrator may forward
a copy of the application to the business
entity originating the in-

1 formation requested, provide that business entity ten
2 days to transmit to the Administrator any factual infor-
3 mation related to the application that the entity be-
4 lieves the Administrator should consider before acting
5 upon the application, and inform the entity regarding
6 the Administrator's intention to approve the application
7 15 days before the actual release of the information
8 from the reading room. The Administrator's decision
9 with regard to an application for permission to borrow
10 and remove documents containing information available
11 for disclosure in a reading room shall be
12 subject to judicial review.

13 “(F) Once a person has been granted permission
14 to borrow and remove documents containing informa-
15 tion available for disclosure in a reading room, such
16 person shall not be required to reapply for permission
17 to borrow and remove material as long as that person
18 has complied with the rules and regulations prescribed
19 by the Administrator in subparagraph (B)(iii) of this
20 paragraph. In addition, such person may request and
21 receive and return documents containing information
22 borrowed from a reading room through registered mail.

23 “(G) Except as otherwise provided in this subpar-
24 agraph, all documents containing information available
25 for disclosure borrowed from a reading room shall be

returned to that reading room. Any person that obtains from the reading room a copy of any charts, graphs, tables containing statistical data, summaries, or abstracts or makes notes based upon any study available for disclosure in the reading room need not return such copies and notes and may use such material for any purpose including, but not limited to, participation in administrative, judicial, or legislative proceedings, publication, medical treatment, or evaluating potential health effects of a pesticide. Except for charts, graphs, tables containing statistical data, summaries, and abstracts and notes based upon the available studies, no person may reproduce in any manner any material borrowed from the reading room. If any person knowingly and willfully violates the provisions of this paragraph, that person and any other person upon whose behalf he or she was acting, who knowingly and willfully violates the provisions of this paragraph, may be debarred by the Administrator from any further access to the reading rooms."; and

- 22 (5) amending subsections (f) and (g) to read as fol-
 28 lows:
 24 "(f) DISCLOSURE TO PESTICIDE PRODUCERS.—

1 “(1) Except as otherwise provided in this section,
2 the Administrator shall not knowingly allow access to
3 an Environmental Protection Agency reading room or
4 otherwise disclose information submitted by an appli-
5 cant or registrant under this Act to any employee or
6 agent of any person engaged in, or who intends to
7 engage in, the production of pesticides or to any other
8 person who intends to disclose such data to such
9 person, unless the data submitter has consented to
10 such disclosure. Notwithstanding any other provision of
11 this section, during administrative adjudicatory hear-
12 ings or court litigation a party may, pursuant to an ap-
13 propriate protective order issued by the court or pre-
14 siding administrative official, examine and obtain a
15 copy of data submitted by another person (other than
16 data described by subsections (d)(1) (A) through (C) of
17 subsection (d)(3) of this section), if the party's access to
the data is found to be relevant as
defined by the Federal Rules of Civil
Procedure, in order to allow the party
to participate fully in the hearing or
litigation.

20 “(2) The Administrator shall maintain and make
21 available upon request records containing the informa-
22 tion required by subsection (d)(2)(B)(i) of this section.
23 When data are borrowed and removed from a reading
24 room under this section, the Administrator shall inform
25 the data submitter of the identity of the data and the

1 information furnished by the borrower under subsection
2 (d)(2)(B)(i) of this section.

3 "(g) INTERNATIONAL AGREEMENTS.—Notwithstand-
4 ing any other provision of law—

5 "(1) The Administrator shall not make available
6 for public inspection any document or information con-
7 cerning pesticides if (A) the Administrator obtained the
8 document or information from the government of an-
9 other country (or from an international organization of
10 countries), (B) the government or international organi-
11 zation required the Administrator to agree not to dis-
12 close the document or information to the public as a
13 condition of furnishing it to the Administrator, (C) the
14 Administrator could not otherwise obtain the document
15 or information, and (D) the government or international
16 organization continues to demand that the document or
17 information not be made available for public inspection.

18 "(2) Except for information describing subsection
19 (d)(1)(A) or (d)(2) of this section, the Administrator
20 may disclose information otherwise entitled to protec-
21 tion under this section to the government of another
22 country if that government furnishes assurances ac-
23 ceptable to the Administrator that the government:

24 "(A) will not further disclose the information
25 without the consent of either the Administrator or

1 the applicant or registrant which submitted the in-
2 formation; and

3 "(B) will not use the information to support
4 any decision to grant any license, permit, or other
5 action which allows the production, sale, or distri-
6 bution of a pesticide under that country's laws."

7 **UNLAWFUL ACTS**

8 **SEC. 6.** Section 12(a)(2) of the Federal Insecticide, Fun-
9 gicide, and Rodenticide Act is amended by—

10 (1) striking out "or" at the end of clause (O);

11 (2) striking out the period at the end of clause (P)
12 and inserting in lieu thereof ", or"; and

13 (3) adding a new subparagraph at the end thereof

14 as follows: (See attachment 1)

20 **PENALTIES**

21 **SEC. 7.** Section 14 of the Federal Insecticide, Fungi-
22 cide, and Rodenticide Act is amended by—

23 (1) redesignating subsections (a)(3), (a)(4), and
24 (a)(5) as subsections (a)(4), (a)(5), and (a)(6), respec-
25 tively;

1 (2) adding a new subsection (a)(3) to read as fol-
2 lows:

3 “(a)(3) DISCLOSURE OF DATA TO PESTICIDE PRODUC-
4 ERS.—Any person granted access to data pursuant to section
5 10(d) that violates the provisions of that subsection or who
6 knowingly accepts data prohibited from disclosure under sec-
7 tion 10(d) may be assessed a civil penalty by the Administra-
8 tor of not more than \$100,000 for each document or study
9 obtained or used in violation of section 10.”;

10 (3) amending subsection (a)(4), as redesignated, to
11 read as follows:

24 (4) amending subsection (b)(3) to read as follows:

25 “(b)(3) DISCLOSURE OF INFORMATION.—

1 “(A) Any person, who, with intent to defraud,
2 uses or reveals information relative to formulas of
3 products acquired under the authority of section 3,
4 shall be fined not more than \$100,000, or imprisoned
5 for not more than 3 years, or both.

 “(B) Any person granted access to data
 under section 10(d) that knowingly and willfully
 allows the data to be sold or otherwise made
 available contrary to the provisions of section 10
 of this Act to any other person engaged
10 in the production of pesticide products or any employee
11 or agent thereof in violation of such section shall be
12 fined not more than \$100,000 or imprisoned for not
13 more than 1 year or both.

14 “(C) Any officer or employee of the United States
15 or any State or former officer or employee of the
16 United States or any State, who, by virtue of such em-
17 ployment or official position has obtained possession of,
18 or has access to material the disclosure of which is
19 prohibited by section 10, and who, knowing that dis-
20 closure of such material is prohibited by such section,
21 willfully discloses the material in any manner to any
22 person not entitled to receive it, shall be fined not
23 more than \$100,000 or imprisoned for not more than 1
24 year, or both. For the purpose of this subparagraph,
25 any contractor with the United States who is furnished

1 information as authorized by section 10(e), or any em-
 2 ployee of any such contractor, shall be considered to be
 3 an employee of the United States.

4 "(D) Section 1905 of title 18 of the United States
 5 Code shall not apply with respect to the publishing, di-
 6 vulguing, disclosure, or making known of, or making
 7 available, information reported or otherwise obtained
 8 under this Act. Nothing in this Act shall preempt any
 9 civil remedy under State or Federal law for any disclo-
 10 sure wrongful under section 10."

11 JUDICIAL REVIEW

12 SEC. 8. Section 16 of the Federal Insecticide, Fungi-
 13 cide, and Rodenticide Act is amended by adding at the end
 14 thereof a new subsection as follows:

15 "(e) Any person claiming to be aggrieved by misuse of a
 16 pesticide may bring suit in a United States district court
 17 having jurisdiction of the parties for damages, equitable
 18 relief, and reasonable attorney's fees and costs, including
 19 expert witness fees."

20 EXPORTS

21 SEC. 9. Section 17(b) of the Federal Insecticide, Fungi-
 22 cide, and Rodenticide Act is amended to read as follows:

23 "(b) CANCELLATION NOTICES FURNISHED TO FOR-
 24 EIGN GOVERNMENTS.—Whenever a registration, or a can-
 25 cellation or suspension of the registration of a pesticide be-

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 available

Attachment II

S-540
71:3127**"Subtitle G—Miscellaneous Provisions****"Employee Protection**

"Sec. 7001. (a) General.—No person shall fire, or in any other way discriminate against, or cause to be fired or discriminated against, any employee or any authorized representative of employees by reason of the fact that such employee or representative has filed, instituted, or caused to be filed or instituted any proceeding under this Act or under any applicable implementation plan, or has testified or is about to testify in any proceeding resulting from the administration or enforcement of the provisions of this Act or of any applicable implementation plan.

"(b) Remedy.—Any employee or a representative of employees who believes that he has been fired or otherwise discriminated against by any person in violation of subsection (a) of this section may, within thirty days after such alleged violation occurs, apply to the Secretary of Labor for a review of such firing or alleged discrimination. A copy of the application shall be sent to such person who shall be the respondent. Upon receipt of such application, the Secretary of Labor shall cause such investigation to be made as he deems appropriate. Such investigation shall provide an opportunity for a public hearing at the request of any party to such review to enable the parties to present information relating to such alleged violation. The parties shall be given written notice of the time and place of the hearing at least five days prior to the hearing. Any such hearing shall be of record and shall be subject to section 554 of title 5 of the United States Code. Upon receiving the report of such investigation, the Secretary of Labor shall make findings of fact. If he finds that such violation did occur, he shall issue a decision, incorporating an order therein and his findings, requiring the party committing such violation to take such affirmative action to abate the violation as the Secretary of Labor deems appropriate, including, but not limited to, the rehiring or reinstatement of the employee or representative of employees to his former position with compensation. If he finds that there was no such violation, he shall issue an order denying the application. Such order issued by the Secretary of Labor under this subparagraph shall be subject to judicial review in the same manner as orders and decisions of the Administrator or subject to judicial review under this Act.

"(c) Costs.—Whenever an order is issued under this section to abate such violation, at the request of the applicant, a sum equal to the aggregate amount of all costs and expenses (including the attorney's fees) as determined by the Secretary of Labor, to have been reasonably incurred by the applicant, or, in connection with, the institution and prosecution of such proceedings, shall be assessed against the person committing such violation.

"(d) Exception.—This section shall have no applica-

tion to any employee who, acting without direction from his employer (or his agent) deliberately violates any requirement of this Act.

**Microfilmed From
Best Available Copy**

PREPARED STATEMENT OF GEORGE COLING, URBAN ENVIRONMENT CONFERENCE, INC.

Chairman Brown and members of the Subcommittee, I am George Coling, Director of the Urban Environment Conference, Inc. (UEC), an alliance of labor, minority and environmental organizations. Since our founding in 1971 by the late Senator Philip A. Hart of Michigan, the Conference's top priority has been to prevent environmentally- and occupationally-caused disease. We have specialized in organizing a wide range of educational programs, including publications and audio-visual productions, conferences, training sessions and technical assistance on scientific issues. The purpose of these programs is to help citizens understand the nature of toxic chemicals in the community and work environment, the threat to health that these chemicals pose and, most importantly, how citizens can reduce the health risks of toxics. Environmental and occupational health problems are most severe among minorities. Accordingly, UEC has focused our educational efforts on meeting the educational needs of Black and Latino citizens. In all, we service a network of some 200 locally-based citizen education organizations, probably half of whom serve or represent minority constituencies. It is from UEC's eleven year record of assisting and working with such organizations from all across the country and our intimate knowledge of their experiences that I speak.

First of all, exposure to pesticides is a real community problem among minority citizens and working people of this nation. A few examples in which UEC has been directly involved illustrate this problem. In Shelby County, Tennessee, over 100 toxic waste dumps, many of them primarily pesticide wastes, have absolutely plagued the community. The dump situation is probably worse in

the Black neighborhood of Hollywood. Citizens there have been severely impaired and have been clamoring for information on the nature of their disease and what caused it. Civic groups like the Memphis Urban League and the Frayser Health and Safety Committee have had no prior experience in this area, but are striving daily to provide citizens with technical information on pesticides and other toxic hazards.

In El Monte, California, the Father Lopez Center, a citizenship training and low income community service group, has identified an increasing need among its mainly Spanish-speaking clientele for information on pesticides and toxics. The Center's radio shows, toxics education in citizenship training classes and a bilingual slide show have partially met this need, but it continues to grow as more and more citizens become sick.

In Rensselaer, New York, over a period of several years not a single normal baby was born to the all male workforce of a plant which produced pesticides and other chemicals. These workers and the International Chemical Workers Union of which they were members used EPA registration data to identify a pesticide, made impurely at the plant, as the almost certain causative agent of the birth defects. Registration data from EPA was also used to find out where else the pesticide in question was manufactured. The problem in Rensselaer was ameliorated as a result of the action taken by the workers.

There are many other cases from suburban Long Island to rural Mississippi where we have worked in which citizens have had a pressing, immediate need for information on health effects of pesticides and other toxics. These citizens have no academic interest in this infor-

mation. They also have no financial or competitive interest. These people are sick or their children are sick or even aborted or stillborn. They live in fear in an increasingly toxic environment.

Now these Americans, and I estimate they number in the millions, do not for the most part, use or interpret raw data on health effects of pesticides. They rely on service organizations like ours and others, the medical and public health professions, the academic community, and others with technical and educational skills to help them. Nevertheless, disclosure of pesticides testing data is at the base of their finding out about the nature and degree of threat to their health from pesticides.

Full, easy and prompt access to pesticide testing data, even if second hand through supporting organizations, is a necessary condition for Americans, and particularly Blacks and Latinos who are a highest risk to environmental disease, to take control of their health, to stop the poisoning, to put an end to the birth defects, and to temper the worry and fear.

In light of the above situation, UEC finds the proposed amendments (HR 5203) to Section 10 of FIFRA no less than a giant step backward for public health. They are totally unacceptable and should be rejected with haste by this Subcommittee. Here are a few of the reasons for doing so.

1. The language establishing, in effect, screening of reading rooms applicants by industry and no review of an EPA Administrator's decision to bar access to the reading room is an affront to human dignity. That Nick C., a worker in that Rensselaer pesticides plant whose toddler son had \$300,000

major heart surgery, or his representative, should be subject to anyone's screening in his attempt to find out what happened to his son is a travesty.

That Ann J., who lives near a pesticides dump in Memphis and whose hair is falling out, could be denied opportunity to research her case and have no appeal is preposterous.

2. The language restricting free and open discussion of non-trade secret data is inherently a threat to public health. Workers initiated the studies and events leading to most, if not all, of the major occupational health news stories of the past decade. These incidents -- vinyl chloride, oryzalin, and the like -- focused public, scientific and regulatory pressure on the prevention of job-related disease and brought some relief to victims and their families. In each of these all too numerous cases, free and open discussion of non-trade secret data played an essential role. Restricting this discussion will damage the process by which new incidences of occupational, and I suspect environmental, diseases are identified and lives are saved.

3. The proposed amendments do not specify a time frame in which EPA must provide information to citizens. Health problems as serious as many of those caused by pesticides demand that a well-defined time limit be specified. Furthermore, not to have such a requirement is an incentive towards unresponsive government with which we must constantly fight.

4. The proposed penalty system, restrictions on discussion of data, general poor access to data and screening provisions in HR 5203 would have a chilling effect on citizens who need to find out what is happening to their health. These cynical proposals would discourage citizens from inquiry, self-help and hope. I cannot think of a better example of proposed legislation that beats down the American spirit and fosters a hopelessness and apathy in its place than these amendments.

Members of the Subcommittee, I strongly urge you to reject the proposed amendments to Section 10 of FIFRA, totally and immediately. The present Section 10 adequately protects trade secrets and insures the public's right to know about hazards from pesticides. This language is well balanced and has no major deficiencies. It should be retained as presently written.

On a closing note, the language protecting workers who participate in proceedings under FIFRA from possible employer retaliation needs upgrading. UEC has done a study of anti-retaliation clauses in health and safety and environmental laws. The most protective clause is that found in Section 105(e) of the Mine Safety and Health Act. We urge that similar language be included in FIFRA.

Thank you for the opportunity to submit our views on these crucial matters.

AMERICAN SEED TRADE ASSOCIATION, INC.

asta
first - the seed[®]

OFFICE OF THE EXECUTIVE
VICE PRESIDENT

HAROLD D. LODEN
Suite 964, Executive Building
1030 15th Street, N.W.
Washington, DC 20005
Telephone (202) 223-4080

February 22, 1982

The Honorable George E. Brown, Jr.
Chairman
Subcommittee on Department
Operations, Research and
Foreign Agriculture
Committee on Agriculture
U.S. House of Representatives
Washington, D.C. 20575

Dear Mr. Chairman:

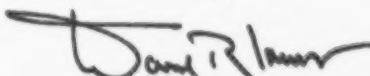
The American Seed Trade Association wishes to compliment you and the Committee for your diligent and tireless efforts to find an acceptable solution to several key pesticide issues during the extended FIFRA reauthorization process. Our Association has not taken an active role in the process in hopes that the parties directly concerned could find a common solution. The introduction of H.R. 5203 raised several new issues that have not been a part of the debate which has taken place over the past year.

We oppose the inclusion of Section 8 in H.R. 5203, which adds a "private right of action" provision. Every precaution needs to be taken to protect the health of individuals who enter a field to work after the application of a pesticide. However, studies have shown that a number of individuals who thought they had been poisoned by pesticides were, in fact, suffering from a skin rash that was caused due to an allergy triggered by a particular crop. If Section 8 were a part of the law, these unwarranted claims could lead to expensive litigation, as has been the case in similar circumstances.

We agree with Dr. John Todhunter, Assistant Administrator for Pesticides and Toxic Substances, EPA, when he stated during testimony on H.R. 5203 before your committee on February 4, 1982 that "guidelines (for reentry) may or may not be the most effective means to accomplish the stated goal of the amendment (Section 13). Worker and applicator protection are more fundamentally addressed in registration, reregistration, or cancellation processes."

I would appreciate your making this letter a part of the hearing record.

Sincerely,



David R. Lambert
Assistant to the
Executive Vice President
Legislative & Regulatory Affairs

DRL/emw

AMERICAN SEED TRADE ASSOCIATION, INC.

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February 23, 1982

OFFICE OF THE EXECUTIVE
VICE PRESIDENT

The Honorable William C. Wampler
Subcommittee on Department Operations,
Research & Foreign Agriculture
Committee on Agriculture
U.S. House of Representatives
2407 Rayburn House Office Bldg.
Independence & South Capitol SE
Washington, DC 20515

HAROLD D. LODEN
Suite 964, Executive Building
1030 15th Street, N.W.
Washington, DC 20005
Telephone (202) 223-4080

Dear Mr. Wampler:

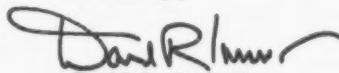
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We would appreciate your making this letter a part of the hearing record.

Sincerely,



David R. Lambert
Assistant to the Executive Vice President
For Legislative and Regulatory Affairs

DRL:rvb

CITIZENS FOR ENVIRONMENTAL QUALITY, INC.
 2737 25A STREET
 CLARKSTON, WASHINGTON 99403
 1/5091758 5796

September 1, 1981

a non profit educational organization

Representative Thomas Foley
 1301 Longworth House Office Building
 Washington, D.C. 20515

Dear Mr. Foley,

I am writing asking you to introduce amendments to this years FIFRA Reauthorization Bill which would strengthen the public's right to know the effects of pesticides to which they are exposed to daily. Such amendments are desirable and necessary for a variety of reasons:

The credibility of EPA and industry in the testing area has been severely damaged by incidents such as those involving Industrial Biotech Laboratories (see attached NCAP News, Winter, 1981). Only full public disclosure can reassure the public.

The next edition of NCAP News will focus on similar problems with several other laboratories, as gleaned from EPA's October 19, 1979, "Health-Effects Data Quality Status Report." It appears that very little valid data exists to support claims of health and safety for many marketed pesticides.

There is a severe problem in the area of the so-called "inert" ingredients of pesticides. Monsanto Corporation's herbicide Roundup is a good example. As the enclosed NCAP News article shows, Roundup is mixed with an unidentified surfactant that causes severe testicular defects in rabbits at normal use rates (NCAP News, Fall, 1980). Even knowing this EPA registered Roundup for forest and home use.

EPA recently moved to reclassify 114 active pesticide ingredients as "inert inactive ingredients for the expressed purpose of exempting them from testing requirements (Chemical Regulation Reporter, April 24, 1981, pp. 83, 94-95). The list includes such chemicals as xylene, which produced positive evidence of mutagenic effects in recent National Cancer Institute studies.

In spite of a supreme court decision upholding the public's right to review health and safety data on active ingredients (Union Carbide v. Costle [no.80-1085, March 23, 1981]), EPA is still refusing to provide such data to the public on grounds of trade secrecy.

Therefore, we ask you to introduce the following amendments to FIFRA:

- (1) FIFRA §§ 10(d)1 C&D should be repealed. These provisions have protected the identity and tests for "inert" ingredients.
- (2) Repeal FIFRA § 3(c)8. EPA has interpreted this section as requiring preventing them from removing

a pesticide from the market for lack of health and safety data. This key section has created an incentive for industry to stall the reregistration process and the development of new data. In its place, establish a requirement that a pesticide's use must be restricted to use by a certified applicator until it has been fully reregistered unconditionally.

- (3) Add the following amending language to FIFRA § 3(f)2: "...unless the pesticide is in the registration standard development process." This removes the requirement that courts view registration as prima facie evidence that the pesticide complies with the registration provisions of the Act. It also establishes a strong incentive for registrants to get their chemicals moving through the process as rapidly as possible. It might be advisable to also add language requiring that chemicals in the registration standard process as of January 1, 1981 not be removed from that process except through satisfaction of the testing requirements.
- (4) Congress should require that expedited court review be required for any industry claim of trade secrecy. Similarly, EPA should be required to diligently defend the public disclosure provisions of the Act.
- (5) There has been blatant venue shopping by industry in bringing reverse FOIA lawsuits to prevent public disclosure of registration data. Congress should require that reverse FOIA suits to prevent public disclosure be brought in the same judicial district in which the original requestor resides or has his or her principle office.

If your staff needs any assistance in these issues I recommend they contact Mr. Paul Merrell at Route 2, Box 190, Tidewater, Oregon 97390. Mr. Merrell can be reached by telephone at 503-528-7151.

I would appreciate it if you would keep both Mr. Merrell and myself posted on the progress of this years FIFRA Reauthorization Bill.

Respectfully,

Georgia E. Hoglund
Executive Director

enclosure: (2)

cc: Paul Merrell

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CALIFORNIA LEGISLATURE

Assembly Rural Caucus

JOHN E. THURMAN
 CHAIRMAN
 27TH ASSEMBLY DISTRICT

STATE CAPITOL
 ROOM 2061
 TELEPHONE: (916) 443-1918
 CAUCUS CONSULTANT
 PHILIP DOWD
 CAUCUS SECRETARY
 MARY KUK

September 2, 1981

Honorable George E. Brown, Jr.
 Chairman, Agriculture Subcommittee
 on Department Operations, Research
 and Foreign Agriculture
 2342 Rayburn Building
 Washington, D. C. 20515

Dear Congressman Brown:

As members of the Rural Caucus of the California Legislature, we wish to make our position known as to Section 24 of the Federal Insecticide, Fungicide and Rodenticide Act which you currently have under consideration.

The experience of California agriculturists, as relayed to us by our constituents, clearly indicates that Section 24 needs mending to prevent unnecessary delays in the registration of needed crop protection chemicals. It is also in the interest of the taxpaying public of California that duplication of tests and procedures already adequately covered by the Environmental Protection Agency not continue as a routine practice of the California Department of Food and Agriculture.

It is our sincere hope that you will keep these paramount considerations in mind in resolving the issue of Section 24. We fully understand that there are unique situations in California agriculture that may require procedures above and beyond those imposed by Federal statute. But we believe that such situations

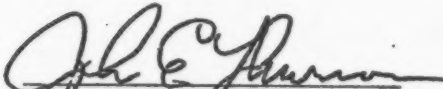
Congressman Brown

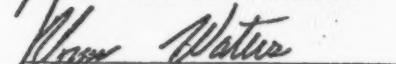
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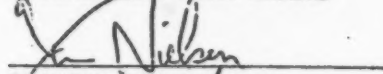
September 2, 1981

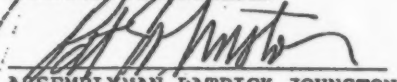
are not common, and that good and sufficient reasons
be proven to exist before such procedures are
instituted.

Sincerely,

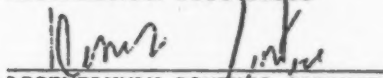

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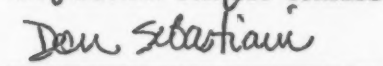

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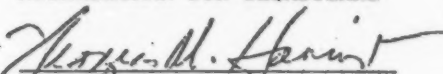

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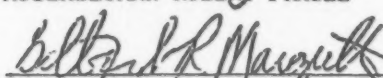

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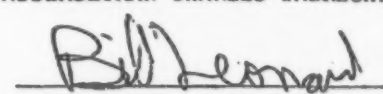

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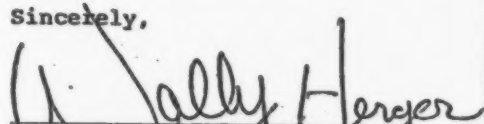

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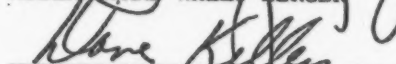

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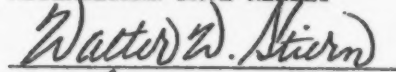

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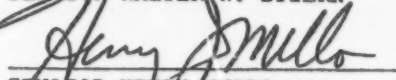

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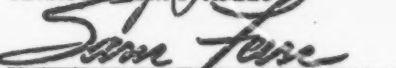

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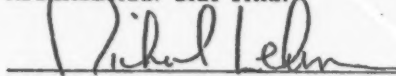

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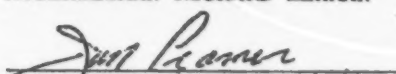

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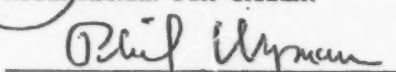

SENATOR WALTER W. STIERN

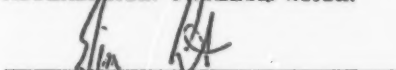

SENATOR HENRY MELLO


ASSEMBLYMAN SAM FARR

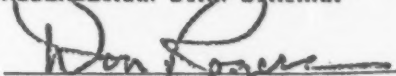

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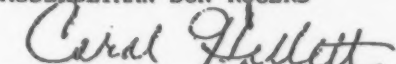

ASSEMBLYMAN JIM CRAMER


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